UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327 Joseph R. Goodwin U.S. District Judge

THIS DOCUMENT RELATES TO:
All Wave II TVT Cases
Jean Fleck v. Ethicon, Inc., et al.
Case No. 2:12-cv-01681
Phyllis Martin v. Ethicon, Inc., et al.
Case No. 2:12-cv-02029
Ramona Phillips v Ethicon, Inc., et al.
Case No. 2:12-cv-02143

VIDEOTAPED DEPOSITION OF
JANET TOMEZSKO, M.D.
June 27, 2016
8:07 a.m.
9599 Skokie Boulevard
Skokie, Illinois

Deanna Amore, CSR, RPR, 084-003999

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I N D E X

EXHIBITS

EXHIBITS

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Exhibit 8	1.9.2012 E-mail; ETH.MESH.08421479	103
Exhibit 9	6.26.2006 Ethicon-Approved Product Pointer Gynecare TVT; ETH.MESH; 00167119	105
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THE VIDEOGRAPHER: We are now on the record.

My name is Milo Savich, and I am a videographer for Golkow Technologies.

Today's date is June 27, 2016, and time is 8:07 a.m.

This video deposition is being held in Skokie, Illinois, in the matter of In Re: Ethicon Inc., Pelvic Repair System Products Liability Litigation, which is being heard in the United States District Court, Southern District of West Virginia, Charleston Division. The case number is 2:12-MD-02327.

The deponent is Dr. Janet Tomezsko.

Will counsel please identify themselves for the record.

MR. JACKSON: Tim Jackson, Wexler Wallace, on behalf of the plaintiffs.

MR. SNELL: Burt Snell, representing Johnson & Johnson and Ethicon.

THE VIDEOGRAPHER: The court reporter is Deanna Amore, who will now swear in the witness, and we may then proceed.

(Whereupon, the witness was duly sworn.)

THE WITNESS: I do.

MR. JACKSON: Good morning, Doctor.

THE WITNESS: Good morning.

MR. JACKSON: Could you please state and spell your name for the record.

THE WITNESS: Janet Tomezsko, T-o-m-e-z-s-k-o.

MR. JACKSON: And, Dr. Tomezsko -- am I pronouncing that correctly?

THE WITNESS: That's correct.

MR. JACKSON: As I introduced myself before we got on the record, my name is Tim Jackson, and I'm from a firm called Wexler Wallace here in Chicago; do you understand that?

THE WITNESS: Yes.

MR. JACKSON: And you're here today to give testimony about the general TVT report you wrote in this case; is that correct?

THE WITNESS: Yes.

MR. JACKSON: And you also wrote three separate plaintiff-specific reports related to this case; is that correct?

THE WITNESS: Yes.

MR. JACKSON: And we'll be addressing some of those later today; is that your understanding?

THE WITNESS: Yes.

MR. JACKSON: And is there any reason you feel you cannot testify fully and accurately today?

THE WITNESS: No.

MR. JACKSON: And if I ask something and it's not clear what I'm asking, I'll ask that you let me know that so I can rephrase it; is that fair?

THE WITNESS: Yes.

MR. JACKSON: And if I ask a question and you answer it, is it fair for me to assume that you understood the question?

THE WITNESS: Yes.

JANET TOMEZSKO, M.D.,

called as a witness herein, having been first duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. JACKSON:

Q. Have you ever had your deposition taken before?

A. Yes, I have.

Q. Okay. In what context?

A. Subsequent treater.

Q. And about how many times?
A. I think three or four.
Q. And are there any other times you've been deposed?
A. No.
(Whereupon, TOMEZSKO Exhibit 1 was marked for identification.)
BY MR. JACKSON:
Q. I'm going to hand you what we've premarked as Exhibits 1 through 3.
If you could just confirm that Exhibit 1 is an accurate copy of the ex -- the general TVT report you provided in this case?
A. It appears to be, yes.
Q. And if you could look at Exhibit 2, please.
(Whereupon, TOMEZSKO Exhibit 2 was marked for identification.)
BY MR. JACKSON:
Q. And can you just confirm that looks like an accurate copy of the CV that would have been submitted with your report?
A. Yes, it does.

(Whereupon, TOMEZSKO Exhibit 3 was marked for identification.)

BY MR. JACKSON:

Q. And if you could just look at Exhibit 3 and confirm that that looks like an accurate copy of the reliance list that was provided with your report in this case.

A. I think we might have a more up-to-date one.

Q. Okay. But is it your understanding that that's the one that would have been submitted with the report?

A. Originally, yes.

Q. Okay. Thank you. Thank you.

And, Doctor, did you review prior to the deposition today?

A. Yes, I have.

Q. And what did you review specifically for this deposition?

A. I reviewed the general medical literature, literature regarding urinary incontinence treatment, TVT-specific literature.

I have reviewed the testimony of medical experts for the cases.

I have reviewed some Ethicon documents and then patient-specific data, but that's not for this report.

Q. Okay. And did you speak with anyone prior to your deposition today specifically in regards to the deposition?

MR. SNELL: Objection. Form. Vague.

Go ahead.

THE WITNESS: Yeah, that's very vague. Can you clarify? Do you mean when the deposition was or...

BY MR. JACKSON:

Q. Did you -- strike that.

You met with your attorney in preparation for the deposition today, correct?

A. Yes.

MR. SNELL: Objection. Form. I'm not her attorney.

THE WITNESS: Oh, that's true. Sorry.

BY MR. JACKSON:

Q. Did you meet with an attorney for Ethicon in preparation for this deposition today?

A. Yes.

Q. And how many times did you meet?

A. Two times.

Q. Okay. And for about how long total?
A. That's a good question. Probably about eight or ten hours.
(Whereupon, TOMEZSKO Exhibit 4 was marked for identification.)
BY MR. JACKSON:
Q. I'm going to hand you what's been marked Exhibit 4, and this is the notice of the deposition today.
A. Yes.
Q. Have you seen that document before?
A. Yes, I have.
Q. Okay. And I see you brought some documents with you. Are you bringing those in response to the document request in the deposition notice?
A. These are the documents that go along with my general report.
Q. Okay.
A. And I don't have any other -- they are just all the literature.
Q. Okay. So I see one -- one large binder on the desk in front of you. Could you just generally tell me what's in that? You mentioned literature.

A. Right. So this is -- this is my -- my CV -- my report, my CV, the materials list and then part of the literature that I reviewed.

Q. Okay. When you say "part of the literature that you've reviewed," are there other documents you reviewed that are not included in this binder?

A. Yes, there are many.

Q. So how did you choose which documents to include in this binder?

A. We narrowed it down to include the ones that were most pertinent and most referenced in this document. We can't include all of them because there are thousands of them. So the ones that are most relevant and most pertinent, the Level 1 data.

Q. And, Doctor, when you say "Level 1 data," what do you mean by that?

A. That is the peer-review classification, Level 1 data is the meta-analysis, systematic reviews of randomized controlled trials considered the highest level data to base clinical opinions on.

Q. Okay. And can we go ahead and we'll mark

the binder she brought with her as Exhibit 5, if that makes sense.

(Whereupon, TOMEZSKO Exhibit 5 was marked for identification.)

BY MR. JACKSON:

Q. Doctor, can you tell me when were you first contacted about providing a report in this case?

A. Oh, several months ago.

Exactly when? The date?

Q. I mean, could you give me a guess of approximately which month?

A. February-March.

Q. Okay.

MR. SNELL: Counsel, can I make a statement for the record?

MR. JACKSON: Sure.

MR. SNELL: Your question about what she brought, you were directing her attention to that big binder. She did bring other stuff in response.

MR. JACKSON: Okay.

MR. SNELL: I just didn't want there to be -- the record to be unclear because we all know that there are multiple boxes sitting over in the corner

and things. So if your question was limited to that, she's answered it, but if you want to know the entirety of everything she brought, it's here for you to look at or ask her about. I just want to make sure there was no unclarity on the record.

BY MR. JACKSON:

Q. Okay. Doctor, your counsel for Ethicon mentioned that there were other boxes brought by you today; is that correct?

A. Yes.

Q. And what -- what is in the other boxes?

A. So in the entirety of the boxes there are -- there is more literature. There are IFUs for the TVT device. There are other Ethicon documents, and there is the patient's -- patient records that we need for the later depositions. I have also thumb drives with data on them, research papers, et cetera.

Q. Okay. And, Doctor, is the entirety of the materials you've reviewed in connection with your reports in this case contained in the binder and the boxes you brought with you today?

A. I would say no. I'm sure there is other documents and literature that I've read that is not

included because there is so much volume of literature I've read through the years, and that is part of my knowledge.

Q. Okay. Thank you.

And, Doctor, I believe you stated a moment ago that you were first contacted about providing a report in this case in February; is that right?

A. Yeah, I think that might be, yes.

Q. And at the time you submitted your report in this case, about how much time had you spent on that report?

A. I would say about 45, 50 hours.

Q. Okay. And do you keep track of your time somewhere?

A. Not -- not a detailed track, no.

Q. Have you submitted an invoice yet for that time?

A. I have submitted an invoice for part of the time, yes.

Q. Okay. Did you bring any billing information with you today?

A. I have the one invoice.

Q. Okay. Is that something you have handy right now?

A. Yes.
Q. Okay. Could I take a look at that?
A. Forgive me. I have to find it.
Can I unclip for a moment?
Q. Of course.
MR. JACKSON: Let's just go off the record for a second.
THE VIDEOGRAPHER: The time is 8:17 a.m., and we are going off the video record.
(A short break was taken.)
THE VIDEOGRAPHER: The time is 8:18 a.m., and we are back on the video record.
BY MR. JACKSON:
Q. Doctor, while we were off the record, were you able to locate the billing information you brought with you today?
A. Yes, I was.
Q. And is that something I could take a look at quickly?
A. Yes.
MR. JACKSON: Can we go ahead and mark that as Exhibit 6, please.

(Whereupon, TOMEZSKO Exhibit 6 was marked for identification.)

MR. SNELL: What's the date of that?

BY MR. JACKSON:

Q. Doctor, we've marked as Exhibit 6 a letter from you to Mr. Burt Snell dated June 1, 2016.

It says "I'm submitting this invoice for my expert witness work from April 1, 2016, through May 31, 2016. The hours include face-to-face meeting, phone conversations and record review, all with an hourly rate of $400 per hour."

Is that your hourly rate?

A. Yes, it is.

Q. "Total hours for this time period is 45. Total fee is $18,000."

Did I read that correctly?

A. Yes, you did.

Q. Okay. Thank you.

And so from April 1 to May 31, it looks like you spent about 45 hours; is that correct?

A. Yes.

Q. And so you said you would have been first retained in this case around February?

A. You asked me when I was first contacted.

Q. When did you first start working on your report in this case?

A. It would have been the beginning of April then.

Q. So that 45 hours is about the entirety of the time you spent?

A. I have -- I'm sure I have spent more than that.

Q. And --

A. That does not -- I'm sorry.

That does not include recent time.

Q. And does that 45 hours include work on both the TVT general report as well as the plaintiff-specific reports?

A. It does include part of both.

Q. Okay. And is it fair to say that since May 31, you've spent additional time working on this case?

A. Yes, I've spent about another month worth of work.

Q. When you say "about a month worth of work," approximately how many hours would that be?

A. Probably another 40 to 50 hours at least.

Q. Okay. Doctor, we have a copy of your CV,

so I won't spend an inordinate amount of time on that, but can you tell me where you went to medical school?

A. I went to Hahnemann University, which is now known as Drexel University in the Tradition of Hahnemann and Medical College of Pennsylvania.

Q. And where in Pennsylvania is that?

A. Philadelphia.

Q. And, Doctor, where did you do your undergrad?

A. Penn State.

Q. And your residency?

A. Lehigh Valley Hospital in Allentown, Pennsylvania.

Q. And what year did you do -- what year was your residency?

A. 1991 to 1995.

Q. And did you have a fellowship?

A. Yes, I did.

Q. And where was that?

A. It was -- at the time it was called Evanston Continent Center here in Evanston, Illinois, under Northwestern University, and now we are called NorthShore University HealthSystem.

Q. And when was -- when was your fellowship?
A. 1995 to 1997.
Q. And what did you do after you completed your fellowship?
A. I went into practice.
Q. And what was your first job in practice? Where did you first practice?
A. I practiced at Advocate Christ Medical Center.
Q. And how long did you work at Advocate Christ Medical Center?
A. Four-plus years.
Q. Okay. And after Advocate Christ Medical Center, what was your next position?
A. I left Advocate to become the director of urogynecology at Northwestern Memorial Hospital for the Northwestern Medical Faculty Foundation.
Q. Okay. And, Doctor, how long did you hold that position?
A. Approximately nine years.
Q. Okay. And after that position, where -- where did you work?
A. Then I came to NorthShore University HealthSystem.

Q. Okay. And, Doctor, that's your current position?

A. That's my current position, yes.

Q. And what's your current title at NorthShore University -- NorthShore HealthSystem?

A. I am just a specialist in female pelvic medicine and reconstructive surgery.

Q. And, Doctor, do you have any board certifications?

A. Yes, I do.

Q. Okay. And what certifications are those?

A. I am board certified in obstetrics and gynecology and in female pelvic medicine and reconstructive surgery.

Q. Doctor, when did you become board certified in obstetrics and gynecology?

A. In -- that's a good question. I have to look at my CV.

Q. Please. Please do.

A. All of these years start to blend together.

Immediately, the first year I could become board certified. So that was November 1 -- I'm sorry -- yes, November 1998.

Q. And, Doctor, you also mentioned you're board certified in female pelvic medicine and reconstructive health?

A. That's correct.

Q. And when did you become board certified in that?

A. 2013, the first year you could become board certified.

Q. And, Doctor, are you licensed in Illinois?

A. Yes, I am.

Q. And, Doctor, have you performed any research in your medical career after medical school?

A. Yes, I have.

Q. And what's the general nature of that research?

A. I have done different research.

I have performed research on medications for overactive bladder.

I have performed surgical research for vaginal prolapse.

And I have done also spinal curvature research having to do with prolapse occurrence, research on nonsurgical management of urinary

incontinence.

Q. And has any of that research been funded by Johnson & Johnson or Ethicon?

A. No, it has not.

Q. Have you been involved in any clinical studies in your medical career?

A. Yes, that's under the research.

Q. Okay. Were any of those studies specific to stress urinary incontinence?

A. Not addressing just stress urinary incontinence, but, yes, they did.

Q. Okay. Can you explain what you mean by that?

A. One of the studies I was involved in was nonsurgical management of urinary incontinence, which included urge and stress urinary incontinence, and then the prolapse studies also include and evaluate urinary incontinence as part of the studies.

Q. And when was the clinical study to evaluate nonsurgical treatments of stress urinary incontinence?

A. So I had -- I participated in -- also medication studies too -- which was in 2006, 2007,

2002, 2004, back to 1999, and then through the years, the other research studies have been from '99 on through 2010, 2012.

Q. And shifting gears a little bit, Doctor, do you currently implant the retropubic TVT product?

A. I do retropubic midurethral slings. Currently, our hospital system does not use TVT products.

Q. And which retropubic midurethral sling product does your hospital use?

A. Right now we use Boston Scientific.

Q. Is there a specific product name?

A. Oh, I'm sorry. Advantage Fit.

Q. Advantage Fit.

So, doctor, have you previously implanted the TVT Retropubic product?

A. Yes, I have.

Q. And when did you begin implanting the TVT Retropubic product?

A. I think I began around 1999.

Q. So around the time it was first introduced; is that fair?

A. That's correct.

Q. And when did you cease using the TVT Retropubic product?

A. Our hospital system switched over based on contracts.

Q. Okay. And --

A. So I believe that was two or three years ago. It was not a physician decision.

Q. So, Doctor, did you use the TVT Retropubic product yourself for about 15 years; is that fair?

A. Approximately, yes.

Q. And how did you come to use it initially in 1999?

A. Can you be more specific with that question?

Q. How were -- how were you introduced to the TVT Retropubic product the first -- prior to the first time you used it?

A. I -- I believe I first learned about it at our scientific meetings.

Q. When you say "our scientific meetings," whose scientific meetings?

A. Thank you.

Our urogynecology scientific meetings such as AUGS or SGS, and then I went to specific

training for it, and my partner at the time was also training at the same time.

Q. And who was your partner at the time?

A. It was Denise Elser.

Q. E-l-s-e-r?

A. Yes.

Q. And, Doctor, you mentioned training of the retropubic TVT device; is that correct?

A. Yes.

Q. And was that an Ethicon training?

A. I do not recall specifically my first training. I assume it was, but I underwent different educational programs, and I'm certain some portion of it was an Ethicon training program.

Q. Okay. Well, specific to the training program you would have attended before you started using the TVT Retropubic device, you don't remember if that was Ethicon or not?

A. I do not remember when or where it was. I'm sure I did attend an Ethicon training at some point, yes.

Q. Okay. But prior to using the TVT Retropubic device for the first time --

A. Prior to using it for the first time, yes.

Q. -- you are certain you attended an Ethicon training? You are certain --

A. I am certain.

Q. Okay, and, Doctor, in the 15 years you've used the retropubic -- I'm sorry. Strike that.

In the 15 years you did use the TVT Retropubic device, approximately how many have you implanted in patients?

A. I think approximately 1,000 to 1,500.

Q. And, Doctor, the retropubic TVT device has been available in both a laser cut and a mechanical cut variation; is that correct?

MR. SNELL: Form as to time.

THE WITNESS: Yes.

BY MR. JACKSON:

Q. Doctor, at the time you've implanted the TVT Retropubic device beginning in 1999 until approximately two or three years ago, have you implanted both the laser cut and the mechanically cut version of the TVT?

A. Yes, I have.

Q. And do you know when you are doing a surgery whether it's mechanical cut or laser cut?

A. Previously?

Q. Yes.
A. At the time I believe our institution switched over from mechanical cut to laser cut, and they only stocked one at the time, you know, one form at the time. So, yes, I did know that we had switched from mechanical to laser cut.
Q. Okay. And do you have an understanding as to approximately when your institution would have switched from mechanical cut to laser cut?
A. I do not recall exactly, no.
Q. Okay. Doctor, just so -- just to make sure I'm clear, is it your testimony that you implanted the mechanical cut TVT and then your institution switched to the laser cut TVT, and you began implanting the laser cut TVT?
A. Correct.
Q. Okay. So, Doctor, was there ever a period of time where you would have been implanting both the laser cut and the mechanical cut?
A. It's possible based on what they had on the shelves. I don't remember specifically.
Q. Okay. Doctor, is it fair to say that when you put a laser cut mesh next to a mechanical cut mesh -- and I'm specifically talking about the TVT

Retropubic -- that you can tell the difference?

A. Inside the package?

Q. No, if they are outside the package.

A. When -- if you were to remove the sheaths?

Q. Sure.

A. So that you can see the mesh?

Q. Doctor, let me ask a better question.

If you're just holding up a mechanical cut TVT Retropubic and a laser cut TVT Retropubic next to each other in your hands, can you tell the difference looking at them?

A. I could not tell the difference, no.

Q. And that would just be looking at it with your -- with your naked eye, correct?

A. Correct.

Q. Okay. Would you need a microscope to tell the difference; is that correct?

MR. SNELL: Form.

Go ahead.

THE WITNESS: I've never looked at them under a microscope myself to try to tell a difference. So I cannot answer that question.

BY MR. JACKSON:

Q. Okay. Doctor, you testified that you --

your best guess is you've implanted approximately 1,000 to 1,500 retropubic TVTs; is that correct?

A. Yes.

Q. And do you have an understanding of what the breakdown would be between the mechanical cut and the laser cut in terms of how many you've implanted?

A. Based on the years, I'd say maybe a slightly higher proportion of mechanical than laser cut, just based on the years that they were produced.

Q. And when you say "based on the years they were produced," I'm just -- I'm just curious how you are coming up with the answer that you think you've implanted slightly more mechanically cut than laser cut.

A. Well, being the last several years that we -- our institution changed brands. So I can count those. So those were years of my doing slings, and I believe they switched over 2005-2006. So the amount of years that I've been using slings altogether, probably from 1999 to 2006 or so, was mechanical cut, and then laser cut after that until our institution switched. So probably it's a

little bit more mechanical cut.

Q. Okay. And, Doctor, is it your understanding that even though your institution switched to the laser cut TVT Retropubic in, I think you said approximately 2006, is it your understanding that the mechanically cut TVT Retropubic was still on the market being sold at that time?

A. At the time, in my discussions, I believe it was not simple for us to get the mechanical cut, and that might have just been an institutional, you know, they like to order one SKU. So I did not have a lot of discussions about what was on the market as what was decided was by the institution, not by the physicians.

Q. Okay. But do you have an understanding as to whether beginning in 2006 when the laser cut mesh was available, was the mechanically cut TVT Retropubic also available at that time? Do you have an understanding?

A. I believe it was.

Q. Okay. So your understanding is from 2006 onward, Ethicon was selling both the laser cut and the mechanically cut TVT Retropubic; is that

correct?

A. No. Initially, I knew that was correct, but I actually am not sure as of today.

Q. So as of today, you're not sure whether Ethicon was selling both the mechanically cut and the laser cut TVT Retropubic from 2006 onward?

MR. SNELL: Form.

THE WITNESS: Correct.

BY MR. JACKSON:

Q. Okay. Doctor, did any of the documents you reviewed in connection with your report in this case inform you as to whether the laser cut TVT Retropubic and the mechanically cut TVT Retropubic were both on the market from 2006 onward?

A. I don't recollect seeing that in the volume of documents, but I can't 100 percent say for sure that it's not there.

Q. Okay. Doctor, in 2009, for example, do you have an understanding of whether both the laser cut TVT Retropubic and the mechanically cut TVT Retropubic were being sold by Ethicon?

A. I do not.

Q. Doctor, other than the retropubic TVT device, have you ever implanted any other TVT

devices yourself?
A. I have.
Q. Okay. And which -- which devices would those be?
A. I have implanted TVT Secur and only a few TVT-O.
Q. Okay. And do you currently implant the TVT-O?
A. No, I do not.
Q. And, Doctor, approximately when would you have implanted the TVT-O and the TVT-S? Do you have a sense of that?
A. The TVT-O was several years after it was first on the market, and then I only did a few. And the same with the TVT Secur, it was probably two or three years after -- it was not immediately after it was on the market, and I only did a few.
Q. Okay. Doctor, do you currently implant any Ethicon products at all?
A. I will use Prolene suture.
Q. In what application?
A. In prolapse repair or just in general suturing wound closure.
Q. Okay.

A. Our hospital is not an Ethicon hospital.
Q. Okay. And, Doctor, just so I'm clear, when you say "suture," you're talking about an individual strand of fiber, correct?
A. Correct.
Q. Okay. And you'd agree with me that a suture is different from a mesh, correct?
MR. SNELL: Form. Vague.
THE WITNESS: A suture is a different form, but it can be of the same material.
BY MR. JACKSON:
Q. Okay. Doctor, when was the first time you ever worked with polypropylene mesh of any kind?
A. I believe my first use of polypropylene mesh was with the retropubic TVT.
Q. And, Doctor, you've mentioned the retropubic TVT, the TVT Obturator, the TVT Secur and the Advantage Fit, correct?
A. Yes.
Q. Are there any other polypropylene meshes that you've worked with in your career?
A. Yes. I have used Gynemesh for prolapse repair. I have used other brands of mesh for sacrocolpopexy also. My Gynemesh would be for

sacrocolpopexy also, and I'm sure I have used other retropubic slings along the way.

Q. Doctor, we previously marked as Exhibit 3 the reliance list you provided with your report, correct?

A. Yes.

Q. And it's a -- it's a big document, correct?

A. Correct.

Q. And have you reviewed every document on that list?

A. I have -- through the years I've seen, I believe, all of the research, and then the Ethicon documents I've had access to and have, I think, briefly reviewed almost every one of them, yes.

Q. Okay. Doctor, as you -- you've mentioned you reviewed some Ethicon internal documents in this case, correct?

A. Yes.

Q. Did you talk to anyone from Ethicon or counsel for Ethicon about which documents you should be reviewing?

MR. SNELL: Objection. I don't think you are

allowed to ask her about my conversations with her. That's work product, and I don't do that between Ed and Dr. Rosenzweig and stuff. So I think that's an improper question as to me.

MR. JACKSON: Sure. I can ask a better question.

BY MR. JACKSON:

Q. Doctor, how did you -- how did you determine which Ethicon documents you were reviewing in connection with your report in this case?

A. I reviewed Ethicon documents that were included in the medical experts' reports, and they're in many of the medical expert reports.

And then I was also supplied with some others.

Q. Okay. Doctor, how did you first become involved in this case?

A. I was contacted by Butler Snow as an expert in the area.

Q. And, obviously, I'm not asking you to violate any attorney-client privilege or anything like that, but can you just describe how you were contacted by Butler Snow? I mean, did you get a

phone call out of the blue?

A. The original contact, I believe, was by e-mail, and I don't -- now I don't remember actually.

Q. Doctor, is it fair to say that someone from Butler Snow contacted you in about February of this year to ask if you might be interested in providing an expert report in this case?

A. Yes.

Q. Okay. And at that time did you have an understanding that they wanted you to provide an opinion that the TVT Retropubic device was safe and effective?

A. It was my understanding that they wanted me to provide my opinion about the TVT Retropubic device.

Q. But did you have an understanding that anybody wanted your opinion to be that the TVT Retropubic device was safe and effective?

A. No.

MR. SNELL: Objection. Form.

Go ahead.

THE WITNESS: Sorry.

No, it was very clear that they wanted my

opinion, no matter what that opinion was.
BY MR. JACKSON:
Q. Okay. So if you had reached the opinion that the TVT Retropubic device was not safe and effective, you still would have submitted a report on behalf of Ethicon in this case?
A. I can't answer that question.
Q. Why can't you answer that question?
A. Because that was not the situation. I don't know what would have happened in a situation that did not occur.
Q. Okay. Doctor, when you used the TVT Retropubic device for approximately 15 years in your practice, did you believe that the TVT Retropubic device was safe and effective?
A. Yes, I did.
Q. And, Doctor, when you were first -- sorry. Strike that.
Doctor, at the time you were first contacted by Butler Snow in approximately February of 2016, did you hold the opinion that the TVT Retropubic device was safe and effective?
A. Yes, I do.
Q. So, Doctor, at the time you began your

work in this case, you already believed that the TVT device, the TVT Retropubic device was safe and effective, correct?

A. Absolutely.

Q. And is it fair to say you haven't come across anything that's changed your mind?

A. That's correct.

Q. Did you see anything or learn anything that gave you concern about the safety and efficacy of the TVT Retropubic device?

A. No, I did not.

Q. Doctor, in regards to the report that we've marked as Exhibit 1, did you type the report yourself?

A. Yes, I did.

Q. Okay. And I believe there are 43 pages. Is that -- does that sound right?

A. Yes.

Q. And, just generally, was it a situation where you reviewed documents and worked on the report as you went along, or you sat down and typed all 43 pages at once?

A. No, I'm a person that gets a portion of the topic I want to evaluate and then review the

most current literature, review, and my also general knowledge and then type that kind of section at a time. I'm a one-section-at-a-time kind of person.

Q. So you worked on it section by section?

A. Yes. Sorry. Yes.

Q. And, Doctor, I think you mentioned when you were listing some materials you read in connection with your report that you looked at the Instructions for Use for the TVT Retropubic device; is that correct?

A. Yes.

Q. Okay. And, Doctor, would you agree with me it is appropriate for a physician that's going to implant the TVT Retropubic device to look at those instructions for use before implanting the device?

A. Yes.

Q. And is it appropriate for a physician who is going to implant the TVT Retropubic device to rely on those instructions for use?

A. I would say we don't rely on the instructions for use because we are trained to do a procedure and know about a procedure. That is a

portion of the information but that is not something we rely on for our expertise and the technique or the procedure.

Q. Okay. Doctor, the Instructions for Use for the TVT Retropubic device list known risks that come with that device, correct?

A. Yes.

Q. Okay. So as a physician, is it your testimony that you did not rely on those warnings?

A. I know of those risks through my years of experience with many operations including different incontinence operations as well as retropubic slings. So that is not the only source of my knowledge. So it's a portion of knowledge, but it's not the only source of my knowledge.

Q. Okay. Doctor, you -- Doctor, is it fair to say that some surgeons who implant the TVT Retropubic device don't have as much experience as you do?

MR. SNELL: Form.

THE WITNESS: I can't answer that. I would assume there is some surgeons who do less surgery than I do.

BY MR. JACKSON:

Q. Doctor, when you started implanting the TVT Retropubic device in 1999, you had limited experience implanting devices as a surgeon; is that correct?

MR. SNELL: Object. Form.

THE WITNESS: At that time in my career, I had extensive experience in all different continence operations, including the most similar pubovaginal sling. So I did have limited experience in the TVT Retropubic but extensive experience all around.

BY MR. JACKSON:

Q. Okay. Doctor, is it the company's responsibility to warn of the risks that come with the TVT Retropubic device?

MR. SNELL: Form.

THE WITNESS: No.

BY MR. JACKSON:

Q. Why not?

A. It's a physician's, as a surgeon's responsibility to know the risks of procedures.

Q. And how does a surgeon learn of the risks that accompany a given procedure?

A. We learn through the literature, through

our research, through our meetings. We learn through our clinical experiences amongst the group, the AGS, SGS, and the fund of knowledge there is regarding procedures.

Q. So if a company -- strike that.

If Ethicon has knowledge of risks that accompany the TVT Retropubic product, does Ethicon have an obligation to warn of those risks?

MR. SNELL: Form.

THE WITNESS: Yes, as a portion of our knowledge.

BY MR. JACKSON:

Q. Okay. And one way they might warn about those risks is through the Instructions for Use; is that correct?

A. Yes.

Q. Would you agree that the Instructions for Use for the TVT Retropubic device is certainly one way that an implanting surgeon can learn about warning information that goes with that device?

A. Yes.

Q. Certainly not the only way but it's one way?

A. It's one way, yes.

Q. Doctor, would you agree that mesh repair for stress urinary incontinence carries with it risks that are not present in other surgeries for stress urinary incontinence?

MR. SNELL: Object. Lacks foundation.

Go ahead.

THE WITNESS: No, I don't.

BY MR. JACKSON:

Q. The risk of mesh erosion certainly is not present in nonmesh surgeries, right?

A. With each of the incontinent surgeries that we perform that we implant either suture or a fascia or a mesh, there is a risk of an exposure or erosion of that material that we use. So it's just a matter of which material has that risk, but they all carry that risk.

Q. But it's your testimony that there are no specific risks that come with the TVT Retropubic device that are not found in other surgeries?

A. When I look at the -- the risk that most people attribute specifically to mesh, since each of the surgeries can also have erosions or rejection of the material, that, to me, all of the

surgeries have the same risks, just a matter of which material, and that's well borne out in the Level 1 literature where they all have been shown to have these -- these types of complications.

Q. Doctor, the -- just generally, the TVT Retropubic device is made out of polypropylene mesh, correct?

A. Correct.

Q. And polypropylene is a synthetic material, correct?

A. Correct.

Q. And the implantation of a synthetic material could lead to a foreign body response, correct?

A. Every material that we implant leads to a foreign body response. It does not mean it's a negative response or a problem. When we operate, it leads to a response.

Q. Doctor, is it your testimony that implantation of a synthetic material and the implantation of the patient's native tissue would result in the same foreign body response?

A. That would be different types of responses for those two different operations.

Q. In what way could the responses be different?

A. There is still a response of the body to the surgery. If you are leaving a material, whether it's synthetic or autologous or xenograft, it will have slightly different responses by the body, but the body still responds to it.

Q. Can a -- Doctor, can the implantation of a polypropylene mesh, such as the TVT Retropubic, result in a chronic foreign body response?

A. I don't believe the literature has borne out that there is a chronic foreign body response to the mesh.

Q. Doctor, are you aware of any peer-reviewed literature which suggests that the implantation of a polypropylene mesh can result in a chronic foreign body response?

MR. SNELL: Object. Form. Overbroad. Scope as to polypropylene mesh to the extent you are talking about prolapse, hernia, something beyond the TVT that she's issued a report on.

Go ahead.

THE WITNESS: So for the TVT Retropubic sling mesh, the literature, the Level 1 literature, shows

longstanding safety without any chronic problems of chronic foreign body response, low rates of complications, erosions, pain, et cetera.

BY MR. JACKSON:

Q. Doctor, are you aware of any peer-reviewed literature regarding polypropylene mesh as used in stress urinary incontinence surgery that can result in a chronic foreign body response?

MR. SNELL: Object. Form. Asked and answered.

THE WITNESS: No, the literature -- the peer review Level 1 literature shows that it's a safe, efficacious product that's tolerated, and if there was a chronic foreign body response that was negative, we should see a much more negative response.

BY MR. JACKSON:

Q. Okay. I understand that. Doctor, I think I'm asking a slightly different question.

I'm just asking whether you are aware of any peer-reviewed literature that suggests there can be a chronic foreign body response in connection with the implantation of a polypropylene mesh for stress urinary incontinence.

Do you understand that question?

A. I do.
Q. Okay.
A. And I think I looked at the literature whether they have proven any chronic foreign body response, and I have not known of any that have proven a chronic foreign body response. So maybe I can't answer whether there is any that suggests a foreign -- chronic foreign body response.
Q. And when you say "proven," what do you mean by that?
A. They -- there is -- through the literature, the Level 1 evidence showing the safety, the low risk of complications with the pain, the erosions that has been looked at and has not shown a chronic foreign body response.
Q. Doctor, would you agree that an erosion is a known risk of the TVT Retropubic device?
A. Yes.
Q. Is there a difference between erosion and extrusion in your mind?
A. According to the IUGA Classification, there is, yes.
Q. And what is that difference?
A. I can pull up the actual document, and

they -- I believe they define erosion as a separation over the mesh versus extrusion is the mesh going into a cavity.

Q. Okay. So, fair to say, in practice, there is a difference?

A. Yes, there is.

Q. Doctor, do you believe the implantation of a TVT Retropubic can result in chronic inflammation?

MR. SNELL: Objection. Asked and answered.

BY MR. JACKSON:

Q. Doctor, I asked about chronic foreign body response before. I'm just asking about chronic inflammation now. Do you understand the question?

A. I believe I do.

So I don't believe that the TVT device will develop into a chronic inflammation that has a clinical effect.

Q. Okay. Doctor, I'm not asking about a clinical effect. Let me ask a better question.

Are you aware of any peer-reviewed literature that suggests that the type of polypropylene mesh contained in the TVT Retropubic device can result in chronic inflammation, whether

you agree with that or not?

A. Again, I look at the literature for what it proves, not what it suggests. So when you say am I aware of the "suggests," I really look at the literature for what is proven, and the literature does not show any chronic inflammation in the Level 1 evidence.

Q. Are you aware of any literature that suggests that the type of polypropylene mesh used in the TVT Retropubic can cause chronic inflammation? Are you at least aware of that literature?

MR. SNELL: Object to form. Asked and answered.

THE WITNESS: I would guess there is something out there, and you can show it to me specifically, if there is something you want me to specifically look at.

BY MR. JACKSON:

Q. Okay. Doctor, if there is literature out there that would show that there is a chronic inflammation associated with the implantation of the TVT Retropubic device, is it fair to say you disagree with that literature?

MR. SNELL: Object. Lacks foundation.

Go ahead.

THE WITNESS: I would disagree with that literature based on the multiple meta-analysis, long-term studies showing the low rate of complications that we actually see such as erosions or pain. So that's what matters.

BY MR. JACKSON:

Q. Doctor, is there -- Doctor, in your practice is there a difference between transient pain and long-term pain?

A. Yes.

Q. Okay. And what is that difference?

A. I think there are multiple definitions for both, but transient pain, in general, means something that is short-lived, might be related to an event; whereas a long-term pain usually is a chronic pain, in our practice, maybe over six months, chronic and persistent.

Q. Okay. Doctor, is it fair to say that transient pain might just be normal pain after an operation that would resolve?

A. Correct. I would call normal pain after an operation a transient pain, as it resolves.

Q. And the fact that a pain might be long-lasting, you'd call it chronic; is that fair?
A. Yes.
Q. Okay. Doctor, would you agree that physicians in your field would use a similar definition of chronic versus transient pain?
A. Yes.
Q. Doctor, do you believe there is a significant difference between transient pain and chronic pain?
MR. SNELL: Object. Form. Vague.
THE WITNESS: I think they are different, yes.
BY MR. JACKSON:
Q. Doctor, you testified that transient pain might just be normal postoperative pain, correct?
A. I'm testifying that normal postoperative pain that occurs from surgery and resolves would be a form of transient pain, yes.
Q. So, Doctor, would you agree that pain that resolves and pain that may last longer than six months are significantly different?
MR. SNELL: Object. Form. "Significantly."
THE WITNESS: Can you clarify "significantly different" for me?

BY MR. JACKSON:

Q. Doctor, in your practice, do you see patients who present with chronic pain that exists six months after an operation?

A. Do I personally see them?

Q. Yes.

A. It's very uncommon.

Q. And, Doctor, in your practice do you see patients who have pain immediately after a surgery that then resolves?

A. Yes.

Q. Okay. And do you view those as significantly different in your practice?

A. There is so many different definitions of significantly different. I think that's what I'm getting hung up on. They are both very bothersome to a patient. They might be managed identically. It's just you are getting me on the significantly different.

Q. So it's the word "significant"?

A. No, it's the word "different." They are both bothersome to patients. They both have to be managed. So maybe clarify your definition of different.

Q. Would you counsel a patient differently if they had short-term pain after a surgery versus if they had continuing pain six months after a surgery?

MR. SNELL: Object. Form. Vague.

THE WITNESS: I can't answer that because pain -- we might have the exact same treatment. So that's hard to answer.

BY MR. JACKSON:

Q. Okay. Doctor, turning to your report that we've marked as Exhibit 1, you cite a great deal of literature in this report, correct?

A. Yes.

Q. Okay. And can you cite any literature in your report that tracks chronic, long-term pain?

A. Chronic, long-term pain in regards to what?

Q. In regards to stress urinary incontinence surgery.

A. As the result of stress urinary incontinence surgery?

Q. Yes.

A. The Cochrane Reviews, the meta-analysis, they all look at pain as one of the outcomes and

the also very low rates of pain. There is different kinds of pain such as dyspareunia.

Q. Well, doctor, I'm specifically asking about chronic, long-term pain. Is it your testimony that the Cochrane Reviews specifically track chronic, long-term pain?

A. I believe that is one of the variables. I know in several of the meta-analyses they look at pain as -- I can find it for you.

Q. Well, no. I'm just asking do you have an understanding whether chronic, long-term pain is specifically tracked as an end point in any of the studies you cite?

A. So there is many definitions of pain. I can pull up one -- I can pull up the studies and read to you their definition of pain.

Q. Well, I'm just asking about chronic, long-term pain.

A. So to clarify, I would have to pull up the study for their definition of pain.

Q. Okay.

A. They all track pain, but what is your definition of chronic, long-term pain?

Q. Well, Doctor, I thought you said your

definition of chronic, long-term pain was pain that persisted six months after surgery; is that correct?

A. That's my definition but --

Q. Doctor, under your definition, are there any studies you cite that specifically track chronic, long-term pain as an end point?

A. So they do all track pain, but I would have to look up the specific definitions for each one.

Q. Okay. So --

A. So I can pull them up, if you'd like.

Q. Well, I'm just asking if you can name a study you cite right now.

A. So, yes, the meta-analysis in the Cochrane review, they do look at pain as part of their review.

Q. And do they specifically track chronic, long-term pain as an end point?

I'm just looking for a yes or no on that.

A. I can't answer that yes or no without looking at the study to know their specific definition of pain.

Q. And, Doctor, do you -- do you rely on the

Cochrane review to support your opinion in your report that the TVT Retropubic device is safe and effective?

A. Yes.

Q. You do.

And is there a specific year of the Cochrane review that you are relying on?

A. There are several years the Cochrane review has come out, and the most recent year is 2015.

Q. And sitting here, do you know whether the 2015 Cochrane review specifically uses chronic, long-term pain as an end point?

A. Again, I have -- I would have to look at the document to look for pain and the definition of pain.

Q. But sitting here right now, is it fair to say you're not sure?

A. Correct. I'm not sure. I'd have to look at the document.

Q. Doctor, is there a randomized clinical trial anywhere for polypropylene mesh to treat stress urinary incontinence that tracks safety as the primary end point?

A. Most of the studies, the primary end points are efficacy, and secondary end points are safety.

Q. So do you know of anywhere that's reversed, where safety is the primary end point?

A. I do not, off the top of my head, no.

Q. Okay. Doctor, are there any studies that you believe support your opinion that the TVT Retropubic device is safe and effective that specifically track dyspareunia as an end point?

A. As a primary end point or the secondary end point?

Q. Let's start with the primary end point.

A. Not that I believe for a primary end point.

Q. And how about as a secondary end point?

A. It's usually tracked as a portion of the data, but I don't believe they are tracked as a secondary end point either, as a specific secondary end point.

Q. So, Doctor, just to be clear, you don't believe there are any studies that support your opinion that the TVT Retropubic device is safe and effective that track dyspareunia as either a

primary or secondary end point, correct?

A. I'm sorry. I believe you asked me if it was a randomized controlled trial. I'm sorry. Maybe I misunderstood.

Q. I think I was asking about just any studies. So let me back up.

Are there any studies that you know of that support your opinion that the TVT Retropubic device is safe and effective that track dyspareunia as a primary end point?

A. So the primary end points are usually done in randomized controlled trials.

So the meta-analysis and the Cochrane Reviews are looking at all the points, not just the primary or secondary end point.

So in terms of the best literature, Level 1 literature, looking at the end points of dyspareunia or pain, those are the best sources because they put together the most literature.

In a smaller, randomized, controlled trial, dyspareunia or chronic pain are not usually a secondary or primary end point because the rate is so low, you'd need just thousands of patients to use as a secondary or primary end point.

So the best literature to look at is the meta-analysis and the Cochrane Reviews because they pull -- they pull all the literature, and then they can look at those, and at that point they are not called primary or secondary end points. They are just part of what they are looking at.

Q. Let me ask a very simple question, and I think we can move on.

Are there any studies that you believe support your opinion that the TVT Retropubic device is safe and effective that specifically track dyspareunia as a primary end point?

MR. SNELL: Object to form. Asked and answered.

BY MR. JACKSON:

Q. I'm just looking for a yes or no.

A. So yes.

Q. What studies?

A. I believe, as I just explained, that the Cochrane Reviews in the meta-analysis that use them as an end point in their research, that those studies support that.

Q. Okay. And it's your testimony that the 2015 Cochrane review specifically tracks

dyspareunia as a primary end point?

A. So, again, not using the word "primary end point." They don't use primary end point. They look at categories.

Q. Doctor, would you agree with me that one or more revision surgeries may be necessary to treat adverse reactions after the implantation of a TVT Retropubic device?

A. Yes.

Q. Doctor, do you believe that the entire TVT Retropubic device can be removed after it's ingrown into a woman's tissues?

A. I believe that you can attempt to remove the entire device, and I'm not sure, on a microscopic level, that you can remove the entire device.

Q. Okay. Doctor, have you personally performed TVT removal surgeries yourself?

A. Yes, I have.

Q. About how many?

A. Do you mean -- can you clarify what kind of removal?

Q. Doctor, have you ever personally removed an entire TVT device yourself?

A. I have never had a case where I needed to remove an entire TVT. I've had to remove a large portion of it.

Q. So fair to say you've never removed an entire TVT device yourself?

A. Correct. I've never been in a situation where I've needed to.

Q. Okay. Do you know anybody who has --

A. Yes.

Q. -- removed an entire TVT device yourself?

A. Sorry. Yes, I have.

Q. And who would that be? Do you know?

A. Is that privileged information?

Q. I mean, I'm -- I'm asking for -- do you know the name of a surgeon who -- who's removed an entire TVT device?

A. Yes, I do.

Q. Okay. And can you tell me who that is?

A. Wouldn't -- I'm concerned about privileged information because those are done so rarely that by naming that physician, it could easily lead to the patient identification because it's so rare that it's done, but, yes, I do.

I will tell you one of my partners

recently removed one.

Q. A partner you currently --

A. Work with, yes.

Q. -- work with recently removed an entire TVT Retropubic device?

A. Well, I'm sorry. I should clarify that. I'm not sure she was certain it was a TVT, but it was a retropubic sling. Sorry. It may not have been a TVT.

Q. Okay. So --

A. But for the technique of removing an entire retropubic sling.

Q. And I'm certainly not trying to violate anyone's privacy or anything, but, Doctor, let me try to ask a simple question here. Sitting here today, do you personally know of anyone who has removed an entire TVT Retropubic device?

A. So beyond the records that I have reviewed where they might have stated that they've removed an entire device, I know of people who removed -- have removed entire retropubic slings, and I'm just not sure if they were TVT slings or not.

Q. So is it fair to say that sitting here today, you can't say that you have -- you can't say

you know of someone who has removed an entire TVT Retropubic device; is that fair?

A. No, because I do know of people who have removed them as part of the record, of patient records as part of the cases.

Q. And is that from the literature?

A. No, patient cases.

Q. Okay. Doctor, would you agree that removing an entire TVT Retropubic device may require aggressive dissection?

A. Yes, I would.

Q. And, Doctor, would you agree that there is no guarantee a surgeon would be able to remove an entire TVT device in the event it needed to be removed?

MR. SNELL: Form.

THE WITNESS: I agree.

BY MR. JACKSON:

Q. Doctor, would you agree that -- let me back up.

Doctor, you said you've personally performed revision surgeries on TVT Retropubic devices; is that correct?

A. I have performed revision surgeries on TVT

as well as other retropubic devices.

Q. Okay. Have you ever seen any pathology reports of the TVT Retropubic mesh that you've personally removed?

A. Yes, I have.

Q. Okay. Have you ever held the -- I'm sorry. Strike that.

After you've removed portions of a retropubic TVT device, have you held the mesh in your hands?

A. Yes.

Q. Has it ever felt stiff?

A. No, it usually feels normal.

Q. Okay. Would you agree that the mesh can be stiff when it's removed?

MR. SNELL: Object. Form. Speculation.

THE WITNESS: I would not know.

BY MR. JACKSON:

Q. Doctor, when mesh is removed, is it possible to just take the mesh out, or do you also have to take out mesh and surrounding scar tissue?

A. It depends on the case.

Q. Doctor, have you seen cases where just TVT Retropubic mesh was removed without any scar

tissue also being removed?

A. So I'm going to speak to my general removal of retropubic slings because it's not always you can say that it's a TVT. So in specific cases I've had to remove some where it's just the sling that comes out, and actually very easily, and sometimes there is surrounding tissue, yes.

Q. Doctor, are you able to answer the question specifically regarding the TVT Retropubic, though, or can you only speak with your experience with all -- all midurethral slings?

A. I -- I have to speak to my experience with polypropylene midurethral slings because we don't always know the original, which sling was originally implanted.

Q. So is it fair to say you may be relying on experience with other products to inform that opinion on the TVT Retropubic?

A. Yes.

Q. Doctor, would you agree that the way to manage complications that are associated with the TVT Retropubic device is typically to remove a portion of the mesh?

MR. SNELL: Object. Form.

THE WITNESS: You would need to be -- to clarify for me on what type of complication you're talking about.

BY MR. JACKSON:

Q. Doctor, in your practice are there complications that can arise after the implantation of the TVT Retropubic device where the way to manage those complications is to remove a portion of the device?

A. Yes, there are complications that might occur where it is necessary to revise a portion of the sling, the TVT device.

Q. Okay. And, Doctor, is it fair to say that a physician, such as yourself, who may be revising a portion of that sling has to make a judgment about how much mesh to remove?

A. Yes.

Q. So it's a judgment call at that point?

A. It's based on the clinical scenario.

Q. So if a doctor decides to remove only a portion of the mesh and some mesh is left behind, you're not here to fault a doctor for making a judgment about how much mesh to remove?

A. Correct.

Q. Doctor, would you agree that in many cases removal of a portion of the mesh does not solve the complications?

MR. SNELL: Form. Lacks foundation.

THE WITNESS: You'd have to put it in context.

BY MR. JACKSON:

Q. Doctor, have you seen patients who have presented to you with erosions of the TVT device?

A. This is where it gets hard for me because I do see patients who have erosions of retropubic slings, and, again, oftentimes, they're not patients that I know which procedure that they had. So I have to say it's a general polypropylene mesh retropubic midurethral sling that I can comment on.

Q. So you can't speak specifically to the TVT Retropubic?

A. I -- I did not go back and look at my cases to fortunately where, to see which ones specifically were TVTs, and then the vast majority of revision surgery that I have done has come in from other physicians.

Q. Doctor, have you specifically treated patients for chronic pain associated with midurethral slings?

A. Can you define what type of chronic pain do you mean? Like whole body pain? Local pain?

Q. Doctor, have you specifically treated any patients for chronic pain using your definition that you believe to be a result of a midurethral sling?

A. I have treated patients for local pain. So being very specific, it's usually at the sling site or mid --

Q. That would be chronic pain?

A. Chronic, more than six months' duration, local pain for retropubic midurethral slings, yes.

Q. And can you say whether you have treated any patients for chronic, local pain at the implantation site following a TVT Retropubic device?

A. I cannot say specifically whether it was TVT.

Q. Okay. And, Doctor, you've mentioned you had to partially remove TVT Retropubic devices, correct?

A. I can specifically say that revision surgeries I've had to do on TVT Retropubic devices were usually just incising a sling for voiding

dysfunction. The other sling surgeries where I might have had to remove a portion, those are the ones I'm not sure whether they were truly TVTs or not.

Q. Doctor, have you ever personally tested a TVT Retropubic mesh for degradation?

A. No.

Q. Okay. Have you ever tested a device of any kind for degradation?

A. No.

Q. Has anyone you worked with ever done that?

A. Not that I'm aware of.

Q. Are you familiar with the chemical process of oxidative degradation?

A. Yes, I am.

Q. And how are you familiar with the chemical process of oxidative degradation?

A. Just through the literature regarding degradation of slings and mesh materials.

Q. Do you know what sort of polypropylene is in the Ethicon mesh --

MR. SNELL: Form.

BY MR. JACKSON:

Q. -- specific to the TVT Retropubic device?

MR. SNELL: Form again.

THE WITNESS: And by what sort of -- do you mean the chemical structure, or do you mean --

BY MR. JACKSON:

Q. Doctor, do you know who manufactures the polypropylene mesh used in the TVT Retropubic device?

A. It's my belief that it's Ethicon.

Q. Doctor, do you know -- back up.

Doctor, the polypropylene mesh is woven out of polypropylene fibers, correct?

A. Correct.

Q. And the polypropylene fibers are made out of a polypropylene resin; is that fair?

A. Yes.

Q. And, Doctor, do you know who manufactures the polypropylene resin that ends up in the mesh in the TVT Retropubic device?

A. I do not know who -- when it starts at the petroleum or wherever it starts, I don't know who manufactures that, no.

Q. Doctor, do you know whether or not pure polypropylene degrades without antioxidants?

MR. SNELL: Object. Form as to scope.

Overbroad.

THE WITNESS: I do not know.

BY MR. JACKSON:

Q. Doctor, are you aware of any established science by chemists that shows that pure polypropylene could degrade without antioxidants?

A. No, I don't have knowledge.

Q. Doctor, do you know which antioxidants are added to the polypropylene in the TVT Retropubic device?

A. I do not.

Q. Doctor, in connection with the preparation of your report, have you undertaken an independent analysis of the antioxidants in the mesh in the TVT Retropubic device?

A. No, I have not.

MR. JACKSON: Why don't we go off the record and take a little break? We have been going a little over an hour.

(Whereupon, a discussion was had off the written record but on the video record.)

THE VIDEOGRAPHER: The time is 9:29 a.m. This is the end of Tape 1. We are off the record.

(A short break was taken.)

THE VIDEOGRAPHER: The time is 9:40 a.m. This is the beginning of Tape 2, and we are back on the video record.

(Whereupon, TOMEZSKO Exhibit 7 was marked for identification.)

BY MR. JACKSON:

Q. Doctor, I've premarked an exhibit while we were off the record, and it's Exhibit 7. And this is the Instructions for Use of the TVT Retropubic device, and that is the 2008 version of those Instructions for Use.

Have you seen this document before?

A. Yes, I have.

Q. Okay. And you'll see, if you turn to the page on the bottom right corner that ends in 0531, do you see that page?

I believe it's the fourth page.

A. Yes, I do.

Q. Okay. And under "Contraindications," do you see that section?

A. Yes.

Q. It says "As with any suspension surgery, this procedure should not be performed on pregnant

patients. Additionally, because polypropylene mesh will not stretch significantly, it should not be performed in patients with future growth potential, including women with plans for future pregnancy."

Do you see that?

A. Yes, I do.

Q. Doctor, would you agree with me that this version of the Instructions for Use doesn't list, as a contraindication, that the TVT Retropubic device should not be used in obese women?

MR. SNELL: Object. The document speaks for itself.

Go ahead.

THE WITNESS: Correct.

BY MR. JACKSON:

Q. And, to your knowledge, does the TVT Retropubic IFU say anywhere that it should not be used in women who smoke, for example?

A. Correct. It does not say it should not be used in women who smoke.

Q. And it doesn't say anywhere that it should not be used in women who have weak connective tissue, for example?

A. Correct.

Q. And is it fair to assume that Ethicon would have known that the TVT Retropubic -- I'm sorry. Strike that.

Is it fair to assume that Ethicon would have known that there is a certain portion of the population who is obese?

A. Yes.

Q. And they didn't say that these woman shouldn't get the device, did they?

A. Correct.

Q. Is it fair to say that if Ethicon thought these women should not get the device, they would have put that in the contraindications?

MR. SNELL: Object. Calls for speculation.

THE WITNESS: Is it fair to say if they thought that it was a contraindication, they would have put it in their -- I would assume so.

BY MR. JACKSON:

Q. And, Doctor, the TVT Retropubic device is obviously intended for women with stress urinary incontinence, right?

A. Correct.

Q. And is it fair to say that women with stress urinary incontinence often have other

comorbidities?

A. Yes.

Q. And the TVT Retropubic device, in your opinion, is perfectly acceptable to implant in women with stress urinary incontinence despite their comorbidities?

A. So there are many potential comorbidities, but, yes, the TVT device is safe with most comorbidities. We'd have to be more specific.

Q. Can you give me an example of a comorbidity that you may see in a patient where you would choose not to implant the TVT Retropubic device?

A. I may not implant a TVT on someone who is about to undergo radiation therapy to the vagina.

Q. Okay. And why is that?

A. Because radiation causes damage to tissues intentionally.

Q. Okay. And is that -- is that common knowledge for any -- any surgeon?

A. Yes.

Q. Okay. And, Doctor, if you see the first bullet point under "Warnings and Precautions" on this same page, it says "Do not use Gynecare TVT

procedure for patients who are on anticoagulation therapy."

Did I read that right?

A. Correct.

Q. And is it fair to say that certainly you don't want to implant a TVT Retropubic device for a patient who is currently on Xarelto, for example?

A. That's correct.

Q. Because they may start bleeding?

A. Correct.

Q. And is that common knowledge among surgeons?

A. Yes.

Q. Okay. Doctor, are you offering yourself as an expert with respect to the warnings that come with the TVT Retropubic device?

A. Yes.

Q. So do you feel that you're an expert in what should and what should not be included in the TVT Retropubic device's warnings?

A. Yes.

Q. Doctor, let's look at the "Adverse Reactions" section towards the bottom of this page.

The second bullet point says "Transitory

local irritation at the wound site and a transitory foreign body response may occur. These responses could result in extrusion, erosion, fistula formation and inflammation."

Do you see that?

A. Yes.

Q. Now, we discussed the definition of transitory to be what would just be normal postoperative pain; is that right?

A. In regards to pain when we discuss transitory pain, yes.

Q. Okay. And Doctor, under the "Adverse Reactions" section, there is no mention of long-term pain, is there?

A. In this specific document?

Q. Correct, just in the four bullet points under the "Adverse Reactions" section.

A. The print is very small. I have to get my bifocal contacts just in the right place.

Correct. There is no mention of pain.

Q. And there is no mention of acute pain, is there?

A. No, I don't believe there is.

Q. Okay. And, Doctor, there is no mention of

pain with intercourse, is there?
A. No, there is not.
Q. And, Doctor, do you know with respect to the TVT Retropubic device's Instructions for Use, whether there was ever any language that one or more revision surgeries may be necessary?
A. Are you talking about all versions?
Q. Correct, yes.
Do you have any knowledge of whether there was ever any language included in the TVT Retropubic IFU that one or more revision surgeries may be necessary?
A. I'd have to look at the last one again, but I don't believe it said "one or more revision surgeries."
Q. And, Doctor, do you know if any of the Instructions for Use for the TVT Retropubic say that there might be permanent injury to the patient which may not resolve?
A. I would have to look at the wording on the -- on the most recent one because that's very vague. It could be any kind of permanent injury. So I'd have to look at the most recent one.
Do you want me to pull that out or --

Q. No, just focusing on Exhibit 7 in front of us, to your knowledge, anywhere in here is there mention of permanent pain that may not resolve in connection with the TVT Retropubic TVT device?

A. No.

Q. Doctor, do you believe Ethicon is responsible for telling physicians how to properly tension the TVT device?

A. No.

Q. And is your answer different if the device is laser cut versus mechanical cut?

A. No.

Q. Do you believe the mechanical cut mesh should be put in with the same amount of tension as a laser cut mesh?

MR. SNELL: Form.

Go ahead.

THE WITNESS: These are, first of all, tension-free procedures. So we don't place them on tension.

If you are talking positioning for the retropubic, I believe the positioning is similar.

BY MR. JACKSON:

Q. Doctor, specifically with regard to the

TVT Retropubic device, do you have an understanding as to whether Ethicon instructs physicians as to how to properly tension the device?

A. Are you talking about whether they are currently instructing physicians on how to properly tension it?

Q. Whether they ever have.

A. As part of the training, at least originally, they did discuss ways to tension, position the mesh.

Q. Okay. And, Doctor, specifically with regard to the TVT Retropubic device, do you believe the laser cut mesh and the mechanical cut mesh are tensioned the same?

MR. SNELL: Form. Asked and answered.

Go ahead.

THE WITNESS: I believe they are positioned the same.

BY MR. JACKSON:

Q. Do you believe they are tensioned the same?

A. Can you then define tension, if I'm misunderstanding?

Q. Well, what's your definition of tension?

A. So I don't tension the sling. I position the sling. So intraoperatively, depending on the case, whether the patient is awake or under general anesthesia, I have different methods of how I position the retropubic slings.

Q. Okay. If a medical director at Ethicon stated that the laser cut mesh and the mechanical cut mesh needed to be tensioned differently, would you disagree with that?

MR. SNELL: Objection. Misstates. Lacks foundation.

THE WITNESS: I -- I would disagree with that as based on clinical practice. I've used many different -- multiple different slings, and I pretty much placed them for the retropubic method all the same. Different methods, whether they have general anesthesia or they are awake.

BY MR. JACKSON:

Q. Okay. So, Doctor, you mentioned earlier from about 1999 to 2006, you implanted the mechanical cut retropubic TVT device, correct?

A. Yes.

Q. And from that point, 2006 until approximately two or three years ago, you implanted

the laser cut version of the TVT Retropubic, correct?

A. Yes.

Q. And did you implant the two versions of the TVT Retropubic the same?

A. Yes.

Q. Okay. Did you have any preference between the mechanical and the laser cut TVT Retropubic?

A. I personally did not, no.

Q. You personally did not?

A. No.

Q. Doctor, would you agree that Ethicon -- I'm sorry. Strike that.

Doctor, you said that when you implant the TVT Retropubic device, there is no tension?

A. I'm positioning it.

Q. And do you position it tension free?

A. The goal is to be tension free, yes.

Q. And how do you test whether it's tension free?

A. Before and after I place it, I check the position of the sling mesh by taking an instrument, hemostat or some type of instrument, and making sure I can pass it between the urethra and the

sling mesh as the sheaths are removed to make sure there is adequate movement between the two, that there is a space between the two that is not pressed up tightly against the urethra.

Q. Doctor, do different surgeons have different ways of testing whether there is tension in the TVT Retropubic mesh?

A. Absolutely.

Q. Doctor, is it -- Doctor, does the -- sorry. Strike that.

Some women are obviously built differently, correct?

A. Correct.

Q. And is variations in female anatomy a factor you have to take into account in determining whether the mesh has been placed tension free?

MR. SNELL: Form.

Go ahead.

THE WITNESS: It's -- the variation in anatomy is more important when actually placing the sling. In the end it doesn't matter how their anatomy looks. I want to make sure the placement is not pressed tightly against the urethra.

BY MR. JACKSON:

Q. Doctor, do you believe that the TVT Retropubic device can curl and rope under tension?

A. I believe that with significant tension, it can curl or rope.

Q. Doctor, if there were Ethicon documents to the effect that the TVT Retropubic mesh could curl and rope, would you want to see those documents?

MR. SNELL: Object. Foundation.

It assumes she hasn't.

THE WITNESS: As a -- just as an implanting clinician, do you mean, as opposed to an expert?

BY MR. JACKSON:

Q. Yes.

A. As an implanting physician, I -- we know all materials can change shape with the wrong use. So it's one of those common knowledge. So I don't need to see any internal materials to know that I can -- you know, I can ruin a suture by tying it wrong. I can ruin an implant by positioning it wrong. So I don't think it's really necessary to see them because it's part of the common knowledge of procedures that you do have to use the device or position it correctly.

Q. Doctor, have you seen any Ethicon documents that would suggest that the TVT Retropubic mesh can curl and rope under tension?

A. Yes.

Q. But you don't think it's necessary to see them?

A. Correct, because you know that's part of procedures.

Q. Okay. Doctor, have you seen any Ethicon documents stating that fraying of the mesh in the TVT Retropubic device is a concern?

A. A concern to who?

Q. To Ethicon.

A. Yes.

Q. Have you seen any Ethicon documents where fraying of the TVT Retropubic mesh was referred to as a defect by Ethicon?

A. I'm not sure whether it was referred as a defect or not. I would have to look at them again.

Q. Okay. Doctor, wouldn't you want to know, especially in a case where you are offering an opinion that the TVT device is not defective, whether or not Ethicon has called its own device

defective?

A. Yes, I'm just -- I'd be glad to relook at those. I'm just not sure of the exact terminology.

Q. But if Ethicon had referred to the TVT Retropubic device as defective, that's certainly information you'd want to review and consider?

MR. SNELL: Object. Foundation.

If you have something, the witness has said she'd look at it. I think you should show it to her. This is improper.

THE WITNESS: Right. So in my -- my clinical opinion is based on the clinical use. My expert opinion is based on the clinical use of the product. So that includes the long-term use of the product, all the studies that show its safety and efficacy in human beings and how we use it and how we actually use it. So that's what my expert opinion is based upon. So whether Ethicon has a memo of some sort, that wouldn't change my expert opinion.

BY MR. JACKSON:

Q. Doctor, you mentioned that your expert opinion is based on the clinical use of this product, right?

A. Correct.

Q. Your expert opinion is also based on your experience and clinical use with other midurethral slings, correct?

A. Yes.

Q. Doctor, if I could ask you to turn, in Exhibit 7, to the page which the last four numbers in the bottom right-hand corner are 0532. I think it's just the next page.

A. Yes.

Q. And do you see the section entitled "Actions"?

A. Yes.

Q. The last sentence of this section says "The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes."

Do you see that sentence?

A. Yes.

Q. Okay. And is that a true statement?

A. According to my review of the literature it has not been shown to suffer from degradation by human enzymes, or I guess this is referring to animal enzymes -- sorry -- animal studies.

Q. Doctor, if basic chemical principles suggest that polypropylene antioxidants degrades, would that make this last sentence of the "Actions" section untrue?

MR. SNELL: Object. Lacks foundation. It calls for pure speculation.

THE WITNESS: No, it would not make it untrue because laboratory studies versus actual in vivo experience, what's happening in the human body can be two different things.

BY MR. JACKSON:

Q. If Ethicon had information that the mesh used in the TVT Retropubic device did degrade, would that make this sentence untrue?

MR. SNELL: Objection. Lacks foundation. Calls for speculation.

THE WITNESS: So this is talking about degradation regarding specific enzymes. So just a vague it does degrade? No, it does not make that untrue. This is talking specifically versus certain enzymes.

BY MR. JACKSON:

Q. Doctor, in your review of Ethicon documents in connection with your report in this

case, did you review any studies that Ethicon did on dogs where they implanted Prolene in those dogs?

A. The Prolene sutures or Prolene mesh?

Q. Either one.

A. Yes, I believe I did.

(Whereupon, a discussion was had off the written record but on the video record.)

BY MR. JACKSON:

Q. Doctor, have you read the deposition of Dr. Thomas Barbolt in connection with your work on this report?

A. I am trying to remember whether I have. Is that a materials witness or...

Q. He was an Ethicon employee.

A. Was that the one testifying for the IFUs, or what would his testimony have been about?

Q. Do you remember any specific testimony -- I'm sorry. Strike that.

Do you remember reading anything Dr. Thomas Barbolt would have said about degradation?

A. Right at this moment I don't remember reading that specific. I might have, but at this

moment I would have to see it to refresh my memory. There were so many.

Q. Fair enough.

Doctor, you're offering an opinion in this case that the mesh in the TVT Retropubic device does not degrade by oxidative degradation, correct?

A. I'm offering the opinion it does not degrade in the human body based on the evidence that we see, the safety and efficacy and the excellent results and then the studies that have tried to prove degradation, like the Clave study has not actually proven the degradation.

Q. Doctor, to your knowledge, have any Ethicon employees testified under oath that the mesh does, in fact, degrade in the body?

A. I'm not sure.

Q. If -- Doctor, if an Ethicon employee had testified under oath that the mesh did degrade in the body, would that make the sentence in this "Actions" section, that "The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes" untrue?

MR. SNELL: Object. Lacks foundation. Calls for speculation.

Go ahead.

THE WITNESS: Would that be regarding --

MR. SNELL: Actually, asked and answered.

Go ahead.

THE WITNESS: Would that be regarding sling mesh or any Ethicon mesh?

BY MR. JACKSON:

Q. The sling mesh in the TVT Retropubic device.

MR. SNELL: Same objections.

THE WITNESS: I don't -- I don't know if their testimony would make something true or not without seeing it and knowing the basis of their testimony.

BY MR. JACKSON:

Q. Okay. Doctor, is it fair to say you cite several studies about the TVT Retropubic mesh in your report?

A. Yes.

Q. Okay. And are any of those studies specific to laser cut mesh?

A. Yes.

Q. Can you tell me which one or ones are specific to laser cut mesh?

A. In discussing the issue of laser cut mesh?

Q. I'm just looking for a specific study on the TVT Retropubic using laser cut mesh.

MR. SNELL: What page are you at?

THE WITNESS: 33.

MR. SNELL: 33.

THE WITNESS: Yeah.

BY MR. JACKSON:

Q. Doctor, is there a specific study on page 33 regarding the TVT retropubic laser cut mesh?

A. I have to refresh my memory. Sorry.

Most of it is talking about the mechanical cut. So are you talking a study of mechanical cut versus laser cut?

Q. Doctor, do you --

A. Because that's -- I don't have that specifically.

Q. So, Doctor, is it your testimony that you do not reference a specific study on the TVT Retropubic device that looks at laser cut versus mechanical cut mesh?

A. For the TVT device specifically, correct.

Q. Yes.

A. At this -- at this moment I would have to

look for that, but I don't believe I reference that, no.

Q. Doctor, could you turn to page 34 of your report, which we've marked as Exhibit 1.

A. Yes.

Q. And I'm looking towards the top of the page, a sentence that says "I have not seen a difference when using mechanically versus laser cut mesh in complication rates in the literature."

Did I read that correctly?

A. Correct.

Q. What literature have you looked at which looks at complication rates of mechanically cut versus laser cut mesh?

A. So that's basically based on time frame of studies. The earlier studies, TVT are done with mechanical cut, and then later studies are done with laser cut. So specifically -- so it's -- in looking at the different versions of the sling, there has been no specific difference that I'm aware of.

Q. Okay.

A. And looking at the larger studies also, there has been no change in the erosion rate or

complication rate after the change where most, I think, institutions probably changed from mechanical to laser cut, started using the TVT EXACT, et cetera.

Q. Doctor, are you just making assumptions about when other institutions made the switch from laser cut and mechanical cut mesh based on your own institution?

A. No, it just was the availability. So especially when people changed to the TVT EXACT, that's laser cut only.

Q. Doctor, you mentioned that later studies only used laser cut mesh, correct?

A. So they included laser cut mesh. So I have to look at each study that you would like to review and be able to tell you from that.

Q. Okay. But, Doctor, sitting here today, can you identify a single study on the TVT Retropubic device that only focuses on laser cut mesh and not mechanical cut mesh?

A. It would be TVT EXACT studies, and I do have some with me. I'd have to find them, pull them out.

Q. You'd certainly agree that the TVT EXACT

is a different product than the TVT Retropubic?

MR. SNELL: Objection. Lacks foundation.

THE WITNESS: I do not agree it is different at all, and it's a -- it just is a thinner needle. That's it. Laser cut and thinner needle, so clinically, it's not a different product.

BY MR. JACKSON:

Q. Doctor, when was the TVT EXACT introduced into the market?

A. I believe it was around 2009. I don't remember exactly. 2009. 2008 to 2010.

Q. And, Doctor, is it your opinion that data on the TVT EXACT, which was introduced in 2009 or 2010, can support the safety and efficacy of the TVT Retropubic device with laser cut mesh?

A. Yes.

Q. And the TVT Retropubic device with laser cut mesh was on the market for multiple years prior to the introduction of the TVT EXACT device, correct?

A. Yes, that's my understanding.

Q. Doctor, are you familiar with a Dr. Carl Gustaf Nillson?

A. In -- familiar in what respect?

Q. Are you aware that Carl Gustaf Nillson was a co-inventor of the TVT Retropubic device?
MR. SNELL: Hold on. Object to foundation.
Did you say co-inventor?
THE WITNESS: Co-inventor, yes.
MR. JACKSON: I did.
MR. SNELL: I'm going to have to object on foundation on that.
THE WITNESS: It was my understanding he was a co-investigator.
BY MR. JACKSON:
Q. Okay. Doctor, have you heard of Carl Gustaf Nillson in connection with the TVT Retropubic device?
A. Yes.
Q. And whether he was a co-investigator or co-inventor, are you aware that he had involvement in the development of the TVT Retropubic device?
A. I'm definitely aware he was an investigator. So into that -- to that, yes.
Q. Doctor, have you read any Ethicon documents where Dr. Nillson offered any opinions about laser cut mesh?
A. I saw some Ethicon e-mails about laser cut

mesh, and I'm -- but I'm not sure if that was with him or not.

Q. Have you read any Ethicon documents where Dr. Nillson expressed an opinion that he would personally not use laser cut mesh because he thought it was too stiff?

A. I believe I did see e-mails or something to that effect, but I would have to review them again.

Q. And do you think it's important to know what Dr. Nillson thinks specifically in regards to the TVT Retropubic device?

MR. SNELL: Form. Vague. Scope.

THE WITNESS: I think -- I don't think it's important in regards to a laser cut versus mechanical cut because of the persistent success and longevity of the use, the long-term success of the procedures being mechanical or laser cut that continue to occur. So I think the literature, Level 1 evidence versus the less than Level 5 opinion of his opinion, that's just his own personal opinion. The Level 1 evidence of the long-term safety and minimal problems make me confident in the laser versus mechanical cut.

BY MR. JACKSON:

Q. Have you -- Doctor, have you seen any Ethicon documents that suggest that fraying of the mesh can result in particle loss?

A. Yes.

Q. And have you seen any Ethicon documents that suggest that that particle loss can result in pain?

A. I believe they were discussing whether it could result in pain or not.

Q. Would whether particle loss can result in pain, is that important for you to know as the physician?

MR. SNELL: Object to form. Lacks foundation.

THE WITNESS: Again, I think the long -- the longstanding literature showing such a low pain rate, less than 2 percent, is really what is more important. So whether there is particle loss or not, whatever it's been shown to have such a low pain rate and dyspareunia rate, that the clinical experience does not substantiate that as a concern.

BY MR. JACKSON:

Q. Doctor, are you aware that particle loss was a reason why Ethicon wanted to use laser cut

mesh rather than mechanical cut mesh?

MR. SNELL: Object to foundation as to Ethicon.

Go ahead.

THE WITNESS: I do believe that was part of the reason.

BY MR. JACKSON:

Q. Doctor, do you know whether Ethicon did any studies themselves to see if there were increased complications due to particle loss?

A. Just specifically due to particle loss?

Q. Yes.

A. I believe there was information regarding particle loss, but I'm not sure of the extent of the studies, how the studies were run -- I'm sorry -- off the top of my head.

Q. Doctor, to your knowledge, has Ethicon done any studies to see if there was any clinical significance to degradation?

MR. SNELL: Objection. Form. Lacks foundation.

The witness has testified there is no degradation in her opinion.

THE WITNESS: So I -- are you talking about patient studies? Animal studies? What type of

studies?
BY MR. JACKSON:
Q. Has Ethicon done any studies, whether patient or animal, to your knowledge, to determine whether or not there is any clinical significance to any degradation?
MR. SNELL: Objection. Lacks foundation as to there being degradation.
Go ahead.
THE WITNESS: Yes, I believe they have done studies.
BY MR. JACKSON:
Q. And which studies are those?
A. So I believe there has been studies on the Prolene sutures. I believe there has been animal studies, dog studies.
Q. To your knowledge, has Ethicon done any studies to see whether or not there was any clinical significance to roping or fraying of the TVT Retropubic mesh?
MR. SNELL: Object. Lacks foundation.
THE WITNESS: You said were there any "clinical studies." So involving patients?

BY MR. JACKSON:

Q. Do you know of any clinical studies?

A. I don't believe there were clinical studies within patients. I believe there were studies just based on bench research on the mesh themselves, the slings themselves, specifically performed by Ethicon that I'm aware of.

Q. And, Doctor, how do you determine clinical significance from a bench study?

A. You can't -- in my view you can't determine true clinical significance just from a bench study.

So you had asked me if there were any clinical studies.

Q. And then you identified some bench studies, right?

A. So I'm not aware of -- so I asked you specifically if you're asking for studies in patients, and then you said "any studies."

MR. JACKSON: Excuse me just a minute.

Why don't we go ahead and mark this as Exhibit 8, I believe.

(Whereupon, TOMEZSKO Exhibit 8 was marked for identification.)

BY MR. JACKSON:

Q. And, Doctor, do you see the subject of this 2012 e-mail is "TVT for Dr. Tomezsko"?

A. Uh-huh.

Q. And does that refer to you?

A. Yes.

Q. Who is Michael Trester?

A. He was an Ethicon rep. I'm not sure if he still is.

Q. Was he an Ethicon rep that you worked with?

A. Or -- or a Gynecare rep. I'm sorry. I'm using the wrong terminology.

Yes.

Q. But he's someone you knew professionally?

A. Yes.

Q. And who is Dorothy Kase?

A. She is an OR person in our NorthShore University HealthSystem, one of the OR staff that is involved in purchasing.

Q. And, Doctor, do you see where it says "Dr. Tomezsko said she would prefer the laser cut

mesh, which is Product Code 810041BL"?

A. Yes, I believe that was for the TVT EXACT.

Q. Okay. Do you see anything on this document to indicate that it was the TVT EXACT?

MR. SNELL: Object. Foundation.

She didn't write this.

THE WITNESS: But my recollection at the time was trend was converting from the classic to the EXACT.

BY MR. JACKSON:

Q. So, Doctor, your testimony is that you believe this refers to laser cut mesh for the TVT EXACT?

A. I believe so, yes.

Q. And, Doctor, is it your understanding that this -- Doctor, I'm sorry.

It says "The hospital is currently ordering Code 810041B, which is the mechanical cut mesh."

Did I read that correctly?

A. Yes.

Q. And which product do you believe that refers to mechanical cut mesh for?

A. The TVT Classic, as I wrote down,

I believe.

Q. And here it says "The laser cut mesh which is Product Code 810041BL," right?

A. Correct.

MR. JACKSON: Okay. Can we mark this as Exhibit 8.

THE COURT REPORTER: 9.

(Whereupon, TOMEZSKO Exhibit 9 was marked for identification.)

MR. JACKSON: Or 9, I'm sorry.

MR. SNELL: Do you have one for me by chance?

MR. JACKSON: Yeah, I do somewhere.

Why don't we just go off the record for a second.

THE VIDEOGRAPHER: The time is 10:22 a.m. We are going off the video record.

(Brief interruption.)

THE VIDEOGRAPHER: The time is 10:23 a.m., and we're back on video record.

BY MR. JACKSON:

Q. Doctor, I've handed you what we marked as Exhibit 9, which is a document that says "Product Pointer Gynecare TVT Tension-Free Support for Incontinence," and this is a June 26, 2006,

document; do you see that?

A. Yes.

Q. And do you see the bold, underlined portion towards the top, where it says "We will continue to have both the mechanically cut and laser cut meshes for sale"?

A. Yes.

Q. And do you see where it says "Gynecare TVT 810041BL"?

A. Yes.

Q. And is that -- is it your understanding that that represents the product code for the laser cut TVT Retropubic?

A. I would assume so.

Q. Okay. And is that the same product code that is listed on Exhibit 8 for --

A. Yes.

Q. So looking at this e-mail, is it still your testimony that that laser cut mesh would be a TVT EXACT?

MR. SNELL: Object. Hold on. Hold on. Object. Asked and answered.

THE WITNESS: The only -- to my recollection, the only change I remember intentionally trying to

make was to the TVT EXACT, and we did change to the TVT EXACT. So I'm not sure -- so to my recollection, I don't remember specifically asking for laser cut versus mechanical cut. I do remember specifically asking for TVT EXACT at some point.

BY MR. JACKSON:

Q. So, Doctor, just to wrap this up, you would certainly disagree with the idea that this suggests you preferred the laser cut TVT to the mechanical cut TVT; is that fair?

MR. SNELL: Form.

THE WITNESS: Correct.

I believe in terms of changing to the TVT EXACT, it was for fellow training, it was easier to train them, less trauma to the patient tissue. There were several reasons I remember why I wanted to change to the TVT EXACT. I do not have an independent recollection of ever having those conversations otherwise.

BY MR. JACKSON:

Q. We can set that aside.

Doctor, on page 32 of your report -- I'm sorry.

On page 31 of your report, I'm looking at

a sentence which begins on the fourth line down that says "The Prolene TVT is an Amid Type I macroporous mesh, which is the generally accepted classification for biomaterials."

Do you see that sentence?

A. Yes, I do.

MR. SNELL: I'm sorry. Counsel, you were on?

MR. JACKSON: 31.

BY MR. JACKSON:

Q. And, Doctor, in your opinion is macroporous mesh safer than microporous mesh?

A. For the indication of a sling?

Q. Yes.

A. Yes, it is.

Q. Doctor, would you agree that in the context of polypropylene mesh for stress urinary incontinence surgery, smaller pore or microporous mesh is less desirable than macroporous mesh for tissue ingrowth?

MR. SNELL: Object. Foundation.

THE WITNESS: Yes.

BY MR. JACKSON:

Q. Doctor, what is the Amid classification that you cite to here?

MR. SNELL: Objection. Vague as to "here."
THE WITNESS: The Amid classification is a classification by Dr. Amid. He classifies the different mesh materials from microporous to -- well, from macroporous to microporous from Type I to Type IV and looking at the pore size and member weave to basically identify the different mesh types.
BY MR. JACKSON:
Q. Doctor, do you have an understanding of when Dr. Amid came out with that classification?
A. I do have his paper with me. I can look that up, the exact year.
MR. SNELL: Would you like her to look that up?
MR. JACKSON: No.
BY MR. JACKSON:
Q. Do you have a general understanding of when that would have been?
A. I believe it was in the '90s, but I definitely could be wrong about that because I'm bad with dates, but I would be glad to look it up for you.
Q. Would it be fair to say that Amid's classification was published prior to the -- prior

to the introduction of the TVT Retropubic device?

A. I would have to look that up to see. I'm sorry.

Q. The TVT Retropubic device was first marketed in 1999, is that --

A. Correct.

MR. SNELL: Foundation. Objection.

Go ahead.

BY MR. JACKSON:

Q. What is your understanding of when the TVT Retropubic device was first marketed in the United States?

A. 1999, I believe, yeah.

Q. And is it your understanding that the Amid pore size classification was developed prior to 1999?

A. I'm sorry. I would have -- I actually have to look that up to make sure.

Q. So sitting here today, you are not certain?

A. At this moment, just with all of this information, I'm -- to be completely accurate, I would have to look it up.

Q. And --

A. Sorry.

Q. Is it your understanding that the Amid classification was developed for mesh and hernia applications?

A. I do believe that's correct. It is for mesh used throughout the body, but I do believe it was for hernia applications originally.

Q. Doctor, what is your -- I'm sorry. Strike that.

Doctor, what support do you have for the statement that the Prolene TVT is a Type I macroporous mesh?

A. By his classification, which is pores are greater than 75 microns, it's usually -- it's a monofilament with a macroporous of, like, 1.1 to 1.3. So it's over the 75 microns.

Q. And the measurements you just gave me, 1.1 to 1.3, where does that come from?

A. It -- it comes from -- so basically, I've looked at it myself, as you can see through -- but I think throughout many studies, they put down the size, the Moalli studies, they put down the size of the pores. So probably the Moalli studies are a very good source.

Q. And, Doctor, do you believe you've done enough diligence to offer the opinion that the TVT Retropubic mesh is macroporous?

A. Yes, I do.

MR. JACKSON: Why don't we mark this as Exhibit 10.

(Whereupon, TOMEZSKO Exhibit 10 was marked for identification.)

BY MR. JACKSON:

Q. And, Doctor, I'll represent to you that this is a -- this exhibit is from Ethicon, and do you see where Ethicon refers to the TVT sling mesh as microporous?

MR. SNELL: Object. Foundation as to Ethicon. This is not an Ethicon -- the way you stated it, you lacked foundation. I'll just leave it at that.

THE WITNESS: So in this classification they wrote down "microporous," but there is no -- they do not have their definition. This is not by Amid classification. So you need to see their definition of sizes.

BY MR. JACKSON:

Q. Doctor, if I suggested that this document suggests that the Prolene is microporous, you'd

disagree with that?

MR. SNELL: Form.

THE WITNESS: By the standard accepted medical classification of Amid, it is macroporous. Someone certainly could have made up their own classification system and called it microporous, but the standard that we go by is Amid, and it's a macroporous mesh.

BY MR. JACKSON:

Q. Doctor, did you mention that you've measured the pore sizes on the Ethicon mesh in the TVT Retropubic device yourself?

A. Yes. It would be -- the mesh itself is see-through, and we show our fellows all the time with a little ruler to see a millimeter.

Q. So that's something you've done --

A. Yes, we did.

Q. -- just with the naked eye yourself?

A. Yes, it's part of teaching.

Q. You do that with a ruler?

A. Yes.

Q. Did you use any microscopic instruments or anything?

A. No, we're just talking about the main, the

larger holes in the mesh, yeah.

Q. And so your visual examination would be based on holding a ruler up to the pores of the mesh?

A. Correct. It's not microscopic. Right.

Q. And how many times have you done that?

A. I don't know altogether. Several -- we teach fellows and residents, new fellow every year.

Q. But your best guess of how many times you've measured those pores?

A. Maybe ten.

Q. Doctor, turning back to page 31 of your report, I'm looking at a sentence just a little lower than we were before, that says "It is often described as large pore, lightweight mesh (AUGS/SUFU 2014 Position Statement)."

Do you see that sentence?

A. Yes, I do.

Q. Doctor, does the AUGS/SUFU 2014 Position Statement specifically deal with TVT Retropubic mesh?

A. It deals with midurethral slings in general.

Q. Right. But it does not deal with -- I'm

sorry. Strike that.

It does not deal specifically with TVT Retropubic devices, does it?

MR. SNELL: Objection. Misstates.

THE WITNESS: So this -- this sentence is describing Type I meshes, and this is relating to Type I meshes in specific. So this sentence of my report is regarding Type I meshes in specific, and then also it refers to the Prolene TVT is an Amid Type I, and then it goes into more specifics about the Type I meshes. So the AUGS/SUFU report is talking about Type I meshes in the future.

BY MR. JACKSON:

Q. And the AUGS/SUFU 2014 Position Statement looks at the TVT Retropubic device as well as other devices from other manufacturers, correct?

A. Correct, because there have been Type III meshes that were used, and so they are specifically supporting the Type I meshes.

Q. And when the AUGS/SUFU 2014 Position Statement discusses Type I mesh, they're referring to products such as the SPARC mesh, perhaps?

MR. SNELL: Objection. Form.

Why don't you pull it out, Counsel, or show it

to her?
BY MR. JACKSON:
Q. Is it your understanding that the AUGS 2014 SUFU Position Statement incorporates data from other products?
A. Yes.
Q. Doctor, do you recall reading Brigitte Hellhammer's deposition testimony in connection with your report in this case?
A. Can you remind me what the testimony was about?
Q. I'm just asking if you recall reading a deposition by somebody with the last name of Hellhammer.
A. I'm bad with names. I remember the content better than the names. I'm sorry.
Q. Do you remember reading deposition testimony --
A. I get called out --
Q. -- of a Ms. Brigitte Hellhammer in regard to pore size of Ethicon'S retropubic TVT meshes?
A. I believe I did review that.
Q. Do you recall anything she said about the pore size of the TVT Retropubic mesh?

A. Can you be more specific?
Q. Are you aware that she testified that the TVT Retropubic mesh was microporous in her view?
MR. SNELL: Object. Lacks foundation. I believe that misstates the actual testimony of the witness.
But go ahead.
THE WITNESS: I would have to look at that context again. I'm sorry.
BY MR. JACKSON:
Q. Doctor, at the time that Ethicon began selling the TVT Retropubic mesh in the United States, do you know whether or not Ethicon had available to it a lighter weight, larger pore mesh?
A. At that time specifically, I -- I'm not sure whether they had already developed a lighter weight, larger pore mesh that they had tested at all in clinical applications. I'm not sure.
For sling application, I mean, specifically.
Q. And, Doctor --
A. I know it had to be in -- in process for applications, though.

Q. Okay. Thank you.

And you said you don't know whether there was a lighter weight, lighter pore mesh that had been tested in clinical applications at the time the TVT was launched, correct?

MR. SNELL: Object. She said "TVT application."

THE WITNESS: So for TVT application, I'm not sure if there had been any clinical use by Ethicon at that point. I don't believe there was.

BY MR. JACKSON:

Q. Would you agree with me, Doctor, that less synthetic material inside the body is preferable?

MR. SNELL: Objection. Overbroad. Lacks foundation.

THE WITNESS: Yeah, I -- I -- can you rephrase? It's very vague.

BY MR. JACKSON:

Q. Doctor, when it comes to polypropylene material in the context of treating stress urinary incontinence, would you agree with the statement that less material is better?

MR. SNELL: Same objection.

Go ahead.

THE WITNESS: I do not agree with that because the study -- remember the name --- the study that compared the Vypro, the thinner meshes for a sling, not compared directly to TVT, they had a higher rejection rate, 4 percent. So I'm not necessarily sure that a lighter weight, larger pore would be as effective for the treatment of stress urinary incontinence if used as a sling. I think that would need to be borne out in more studies.

But the current -- there is one study that looks at the three slings -- the Vypresh -- the Vypro, ULTRAPRO, I think it was, and Vigenis (phonetic), and has been looked at, and it did not show as good equivalence as the TVT Retropubic.

I don't think that's been proven yet.

BY MR. JACKSON:

Q. Doctor, have you seen any Ethicon documents that indicate that less mesh overall was preferred?

MR. SNELL: Object. Vague. Lacks foundation.

THE WITNESS: For what indication?

BY MR. JACKSON:

Q. For treating stress urinary incontinence.

A. So in terms of Ethicon's opinion, I -- I'm not sure, but what matters to me more is what research we have, and what little research we have on that did not show an improvement in outcome. It actually showed worse outcome.

Q. Doctor, throughout your report in this case, you cite a number of complication rates based on literature, correct?

A. Correct.

Q. And --

MR. SNELL: Counsel, if we are going to transition into something else, can I take a break and use the restroom real quick?

MR. JACKSON: Sure. Let's go off the record. Let's take a break.

THE VIDEOGRAPHER: The time is 10:42 a.m., and we are going off the video record.

(A short break was taken.)

THE VIDEOGRAPHER: The time is 10:52 a.m., and we are back on the video record.

BY MR. JACKSON:

Q. Doctor, before we just went off the record, I was asking whether you cite complication rates in your report based on literature.

A. Yes, I do.
Q. Okay. And the numbers for a given complication are not uniform, are they?
Let me ask a better question. I apologize.
Doctor, you cite literature for complication rates for erosion in your report, correct?
A. Correct.
Q. And the erosion rate numbers for the TVT Retropubic device are not uniform from publication to publication, are they?
MR. SNELL: Object. Form.
THE WITNESS: They -- they can vary from publication to publication, yes.
BY MR. JACKSON:
Q. Okay. And why do they vary, in your opinion?
A. Well, I believe there is minimal variation overall. So when you look at the largest -- all the larger studies, all the meta-analysis, all the Cochrane Reviews, the reviews, even amongst the randomized controlled trials, they are fairly consistent at a 2 percent erosion rate. There is a

few outlier studies, and it's hard to explain why they vary, different definitions, usually, of an erosion. They may not be all consistent with their definitions, but when you look at the vast majority of the literature, the large basis of the literature, it's all fairly consistent about 2 percent.

Q. I take it you would disagree with me if I said the erosion rates in the literature vary significantly?

A. So I would disagree based on the larger studies, yes.

Q. Okay. And, Doctor, you cite to the 2015 Cochrane review in your report, correct?

A. Correct.

Q. And that's a meta-analysis, correct?

A. Correct.

Q. And I believe you referred to that before as a Type I evidence, correct?

A. Correct.

Q. And why is a meta-analysis Type I evidence?

A. It's usually Type I evidence because it includes the randomized controlled trials.

Q. And, Doctor, you believe that the 2015 Cochrane review supports your opinion that the TVT Retropubic device is safe and effective, correct?

A. Yes.

Q. Okay. And I believe we stated earlier that the Cochrane review -- I'm sorry. Strike that.

The Cochrane review is a meta-analysis of different studies, correct?

A. Yes, it is.

Q. Okay. And those different studies -- I'm sorry. Strike that.

The Cochrane review that you cite in your report that cites to different studies and looks at different studies includes various midurethral slings, correct?

A. That is correct. It does include varied midurethral slings, but it's heavily weighted upon the TVT data. The vast majority of the data that's used is the TVT Retropubic.

Q. Okay. And there is also data from other devices from other manufacturers in the 2015 Cochrane review that you rely on, correct?

A. Yes, there is.

Q. And so, for example, are you relying on data on the SPARC and other midurethral slings to support your opinion that the TVT Retropubic device is safe and effective?

A. Well, since I'm relying on data from multiple different studies, not just the Cochrane review, that is part of the Cochrane review but, again, the vast percentage of all the literature I'm looking at is TVT Retropubic-based.

Q. But would you agree with me you're looking on -- looking at some literature that relies on the SPARC, for example, and other midurethral slings to support your opinion that the TVT Retropubic device is safe and effective?

A. Yes.

Q. Okay. So what makes you say the TVT Retropubic device is safe and effective based on a different product?

MR. SNELL: Object. Form.

Go ahead.

THE WITNESS: So I'm not doing it based on a different product, and actually, the Cochrane review says the retropubic top-down approach, the

SPARC, is not included as part of their retropubic. They're talking about midurethral slings that are top-up approach. So -- and so the vast majority of the data -- when you look at the other studies -- the Schimpf, Tommaselli -- they are primarily TVT Retropubic studies. So I can say with confidence that this is, you know, this is TVT Retropubic data primarily.

BY MR. JACKSON:

Q. And what other top-up products are included in the 2015 Cochrane review other than the TVT Retropubic device?

A. That's the vast majority. I can --

MR. SNELL: Counsel, I think you said top-up instead of bottom-up --

MR. JACKSON: Oh, I'm sorry. Thank you.

MR. SNELL: -- unless I misheard.

THE WITNESS: He did, but I might have said it too.

BY MR. JACKSON:

Q. What other bottom-up slings are included in the 2015 Cochrane review other than the TVT Retropubic device?

A. Can I look that up for you? Can I --

Q. Certainly.
A. -- bring it up for you?
Do we need to go off the record while I find it?
MR. JACKSON: Sure. Let's go off the record.
THE VIDEOGRAPHER: The time is 10:57 a.m., and we are going off the video record.
(Brief interruption.)
THE VIDEOGRAPHER: The time is 11:03 a.m., and we are back on video record.
BY MR. JACKSON:
Q. Doctor, before we went off the record, I asked you what other bottom-up slings, other than the TVT Retropubic device, are included in the 2015 Cochrane review. We've taken a few moments off the record for you to review that 2015 Cochrane review.
Are you able to answer that question?
A. Yes, so looking through their list, the vast majority of the retropubic-type bottom-up is TVT. There is Vypro, ULTRAPRO, Prolene light mesh, and the Okulu study, just going through them -- they are -- there is an occasion one that just says retropubic, the IV-- IVS similar system, but the

vast majority are TVT retropubic, you know, that are not SPARC or transobturator.

Q. So, Doctor, you listed the IVS, the ULTRAPRO, the Vypro?

A. Correct.

Q. And those are all bottom-up midurethral slings listed in the 2015 Cochrane review?

A. Correct.

There is -- I found -- so there is one study with an ULTRAPRO Vypro, and then there is one study with ObTape and DUPS, which I'm not sure exactly what that is. I'd have to look that up.

And there is another one that just says retropubic. So I'm not sure which study that is. I'd have to look that up. There is some nonspecific language in this summary table that I'm looking at.

Q. And, Doctor, when you see a study that just said "retropubic" and doesn't specify a particular product, do you find that study to reliably inform your opinion on whether the TVT Retropubic device is safe and effective?

A. So that study --

Q. Doctor, I'm just asking generally. I'm

not asking about a specific study.

MR. SNELL: Object to speculation and vague on define.

THE WITNESS: Right.

So I would have to look at that specific document to know whether that's a TVT in itself, but assuming that it's not, since the vast majority of the studies, the vast majority of the patients looked at TVT Retropubic, I can reliably use this as a source for the TVT Retropubic.

BY MR. JACKSON:

Q. We can switch directions and move on.

Doctor, we talked a little bit earlier about the TVT Retropubic Instructions for Use; do you remember that?

A. Yes.

Q. Okay. And do you remember reading the testimony of an Ethicon employee named Meng Chen about the Instructions for Use of the TVT IFU?

A. Yes.

Q. And can you tell me, sitting here, what you remember about that testimony?

A. I believe -- again, I'm not good with the names but the substance of the IFUs -- I believe it

was testimony about what should be included and what shouldn't be included.

(Whereupon, TOMEZSKO Exhibit 11 was marked for identification.)

MR. JACKSON: Is that Exhibit 10?

THE COURT REPORTER: 11.

BY MR. JACKSON:

Q. Doctor, do you recall seeing this document before?

A. I believe I have.

Q. And, Doctor, it says that Meng Chen is the associate medical director; do you see that?

A. Yes.

Q. And that would be the associate medical director of Ethicon; is that correct?

A. Correct.

Q. Okay. Have you ever met her?

A. No, I have not.

Q. Have you reviewed any documents authored by her in addition to this one?

A. I believe I've seen other e-mails regarding this.

Q. Doctor, this message is dated -- I'm sorry. Strike that.

Doctor, do you see that this is an e-mail from Meng Chen dated January 29, 2009?

A. Yes.

Q. And do you see on that January 29, 2009, e-mail where Meng Chen is questioning whether or not the general statement about transitory local irritation is still sufficient?

A. Yes.

Q. And do you see what she says above that, about an hour later? She tells Bryan Lisa, "Pardon me again. From what I see each day these patient experiences are not transitory at all"?

A. Yes.

Q. And do you see that she's talking about the TVT IFU on tape erosion, exposure and extrusion?

A. Yes.

Q. Doctor, do you see toward the top of the page a mention of Dr. Kirkemo?

A. Yes.

Q. Do you know who Aaron Kirkemo is?

A. I recognize the name, but I forget the specific position.

Q. Doctor, are you aware that Meng Chen

recommended that the IFUs be updated to reflect the kind of calls she was getting about permanent pain and chronic pain and the inability to have intercourse?

MR. SNELL: Objection. Lacks foundation. Misstates the evidence.

Go ahead.

THE WITNESS: Those specific words, I -- I did see other documents, but I don't remember if that's what they specifically said.

BY MR. JACKSON:

Q. Doctor, do you see here where it says "Meng Chen, M.D., Ph.D.," "The Associate Medical Director, Worldwide Customer Quality, Ethicon"?

A. Yes.

Q. Do you disagree with the worldwide medical director of Ethicon if she said these things need to be changed to update what is happening?

MR. SNELL: Objection. Misstates the evidence.

Go ahead.

THE WITNESS: I -- in terms of the IFU and what it should specifically say, I think these are all information that implanting surgeons need to know regardless, and it's part of our general medical

knowledge, and it's part of our medical knowledge just as surgeons and from our literature.

So what they feel is important to write in their IFU, I think, you know, is up to them, but because this is erosion and dyspareunia or things that we do know about, whether it's in the IFU or not, we, as surgeons, need to know that, and we don't depend on the IFU for that information. We depend on the research for that information.

BY MR. JACKSON:

Q. Do you believe that the IFU for the TVT Retropubic device should contain information on all known risks?

A. I think it should contain information on known risks. I think it's hard to do all known risks because that would be an extensive -- that would be a document like my binder.

Q. Doctor, if a company is getting reports in postmarket surveillance of permanent pain associated with the TVT Retropubic device, does the IFU need to be updated to include that information?

MR. SNELL: Object. Improper hypothetical. Lacks foundation.

THE WITNESS: So, again, I think that would be

up to the company. This is -- as a surgeon, it is up to us to keep up with the literature and what's going on at our meetings, what we discuss and what we're finding as we have experience with patients regardless of what the IFU says. So, you know, it's up to the company what it should say, but that is not our only source of knowledge.

BY MR. JACKSON:

Q. But I think you agreed earlier, Doctor, that the IFU is certainly a source of knowledge that physicians would rely on?

A. Right, it is a source of knowledge. Yes, it is part of the knowledge.

Q. Doctor, as someone who is offering opinions about which warnings should or should not be included in the IFU for the TVT Retropubic device, how do you believe the decision should be made on what should be included?

A. So you're saying if it was my job to be the one to complete the IFU?

Q. No.

Doctor, I'm saying you're offering opinions in this case about what information or warnings should be contained in the TVT IFU,

correct?

MR. SNELL: I'm going to object. I think you're misstating her opinion. Her opinion is the adequacy, sufficiency of the IFU and what risks are commonly known by surgeons like her. She's not offering an opinion that she would write the IFU in a certain manner.

BY MR. JACKSON:

Q. Doctor, we discussed earlier that the risk of dyspareunia or painful sexual intercourse is not listed in the TVT Retropubic IFU, correct?

A. Correct.

Q. Do you think a woman would want to know if there is a risk, even if it's not causally related, that there is a risk that after she gets the implant, she may experience painful sexual intercourse?

MR. SNELL: Object. Vague. Compound. It asks for what this undefined woman would or would not want to know.

THE WITNESS: I very much agree that a woman would want to know whether dyspareunia was a risk of any surgical procedure that she had, and as a surgeon, that is my job to ascertain the risk of

whatever procedure I'm doing and relay it to the patient. And, again, that doesn't come from a few IFU. There are surgeries that we do that have no IFUs that result in dyspareunia, and we still have to relay that information. So that is not IFU-dependent. That is procedure and surgeon-dependent to relay information to the patient.

BY MR. JACKSON:

Q. Okay. But if Ethicon were getting reports of dyspareunia in postmarket surveillance, do you believe Ethicon had a right to update the IFU to include that information?

MR. SNELL: Form.

THE WITNESS: It has a right to include any information that it would like, of course.

BY MR. JACKSON:

Q. Does Ethicon have an obligation to include information about painful sexual intercourse that they've obtained in postmarket surveillance regarding the TVT Retropubic?

MR. SNELL: Form. Calls for a legal conclusion.

THE WITNESS: I don't know what the legal

obligation is. That's true. I think in terms of how I view it -- again, I know all of this independent of the IFU. So, again, I believe they should put in what they feel is appropriate for clinicians to know.

BY MR. JACKSON:

Q. Well, don't you think as -- I'm sorry. Strike that.

Doctor, you stated earlier that a woman may require multiple revision surgeries after the implantation of a TVT Retropubic device, correct?

A. Yes.

Q. And do you think that's information a woman -- I'm sorry -- do you think that's information a patient of yours would want to know prior to the implantation of the device?

MR. SNELL: Same objection. Foundation.

Go ahead.

THE WITNESS: I do personally think it's standard of care, and it's standard of care in my practice to warn patients that, for multiple different reasons, they may require repeat operations from this procedure, as well as other procedures that I do. So that it is something that

I do warn patients about.
BY MR. JACKSON:
Q. But you're not offering any opinions on whether the risk of multiple revision procedures should have been included in the IFU by Ethicon?
MR. SNELL: Object. Misstates.
THE WITNESS: I find that hard to answer. I'm sorry.
BY MR. JACKSON:
Q. Do you believe Ethicon should have included the risk of multiple revision surgeries following the TVT Retropubic procedure in the TVT Retropubic IFU?
A. I think the -- the risk of multiple revision surgery, being well less than 1 percent, is such a small risk that I don't think they need to include every small risk because, again, we know about these small risks, but that would be up to Ethicon to decide if they felt it was appropriate.
Q. Okay. So, Doctor, I just want to make sure I'm clear. Is it your testimony that because it's a risk that -- I am sorry.
Doctor, is it your testimony that the risk of multiple revision surgeries is a risk inherent

with all surgeries; is that correct?

A. Yes, there is a risk that no matter what incontinence procedure you have, that you could need more than one revision surgery or repeat surgery on that procedure.

Q. And, Doctor, that's common knowledge that any surgeon would know?

A. That is common knowledge for any procedure.

Q. But, Doctor, we talked earlier about how Ethicon warns that you shouldn't implant the TVT Retropubic in patients who are on anticoagulation therapy, correct?

A. Correct.

Q. And that's also common knowledge that any surgeon would know, correct?

A. That is correct.

Q. Okay. So is it fair to say that Ethicon does warn about some things that are common knowledge?

A. Yes, absolutely.

Q. But it's your testimony that warning about multiple revision surgeries after the TVT Retropubic procedure is not necessary because

it's common knowledge?

A. I think the content of the IFU is really difficult because there are so many things that potentially can be contained. So it's, I would say, up to them to -- what they include.

Q. Doctor, turning to the -- I'm sorry.

Doctor, are you aware of brochures for the TVT Retropubic device?

A. Yes.

Q. Okay. And, generally speaking, do you know whether or not the TVT brochure always disclosed the risk of dyspareunia?

A. Oh, I would have to look back at my copies that I have. I do not think it originally did, but I'd have to look at the copy.

Q. Okay. And, Doctor, we established, I believe, that the IFU for the TVT Retropubic is one piece of evidence that an implanting surgeon such as yourself would consider in forming sort of your risk-benefit analysis of the TVT Retropubic; is that fair?

MR. SNELL: Object to form. Misstates, I believe, her testimony.

THE WITNESS: It is part of the information

that we can include.
BY MR. JACKSON:
Q. Okay. And is information contained in the TVT Retropubic brochure also part of the information you would consider?
A. Specifically, I would consider for what? I'm sorry.
Q. Doctor, do you read the TVT -- I'm sorry. Strike that.
Doctor, have you read the TVT Retropubic brochure prior to implanting the TVT Retropubic device in patients?
A. You're talking about the patient brochure --
Q. Yes.
A. -- versus the brochure that's given to providers?
Q. Yes.
A. Yes, I had looked at the patient brochure in the past. I am not sure originally whether I read it prior to or not. I almost think I did not. I don't think they were available initially. That is not something that I routinely use. To me that's not enough information to make any judgments

on as a -- as a surgeon.

Q. Doctor, would it surprise you to know that, for example, there are brochures that existed for a significant period of time that did not disclose the risk of painful sexual intercourse to women?

A. Would that surprise me?

No, it would not surprise me.

MR. JACKSON: Mark this as an exhibit.

(Whereupon, TOMEZSKO Exhibit 12 was marked for identification.)

BY MR. JACKSON:

Q. Doctor, do you recall having seen this document before?

A. I believe I have, yes.

Q. Do you know who Professor Hausler is?

A. I recognize the name. I believe he's one of the European surgeons.

Q. Okay. And do you know who Axel Arnaud is?

A. One of the scientific directors.

Q. Doctor, do you see where Dr. Hausler thought that erosions with respect to the TVT mesh were underreported?

A. Yes.

Q. Do you agree with the rest of that statement, where it says "There can be hidden erosions that are asymptomatic"?

MR. SNELL: Object. Form. Incomplete part of the statement.

THE WITNESS: So he wrote that "Most of the time a hidden erosion is asymptomatic, and neither the patients, nor their sexual partners have -- if any complain, but it might happen that a patient may complain."

So do I agree that he might have felt that way?

BY MR. JACKSON:

Q. Sure.

A. You know, per -- Axel said that's what Dr. Hausler said to him.

Q. Doctor, do you believe that asymptomatic erosions are a possibility following the implantation of a TVT Retropubic mesh?

A. Yes.

Q. And do you believe that those asymptomatic erosions can sometimes turn into symptomatic erosions many months later?

A. That's hard -- that's hard to speak to because asymptomatic erosion, no one knows is

there, and it hasn't been identified. So I can't say whether that's the one that would turn into a symptomatic erosion or not. There is no study that's been done on that.

Q. Doctor, is it fair to say that the body continues to react to the mesh as long as the mesh is in the body?

MR. SNELL: Objection. Vague. Overbroad. Asked and answered.

THE WITNESS: No, I would disagree with that.

BY MR. JACKSON:

Q. Doctor, do you see the sentence in the paragraph that starts "I explained," that says "I also indicated that we want to be very careful with any modifications to our tape, since a change in the mesh would obsolete all the long-term clinical results we have about the procedure."

Do you see that sentence?

A. Yes, I do.

Q. And can you tell me what, if anything, you know about that statement?

MR. SNELL: Object.

THE WITNESS: It implies that they don't -- they have to be careful of any changes because then

that will make it into a different product.

BY MR. JACKSON:

Q. When you say "they," you mean Ethicon?

A. If Ethicon changed it, it would make a different product, and then -- and, as surgeons, we don't automatically say "This product is the same as that one. They are different." So then we -- you have to start fresh, and they had already had good success with their product.

Q. Doctor, we can put that aside. I'm done with that one.

Doctor, do you know Dr. Roger Goldberg?

A. Yes, I do.

Q. Does he work at NorthShore Hospital with you?

A. Yes, he does.

Q. And do you just know him professionally?

A. Yes.

Q. Doctor, do you know a Dr. Gregory Bales at the University of Chicago?

A. Yes, yes, I do.

Q. And do you just know him professionally?

A. Yes, just professionally.

Q. And how do you know Dr. Bales

specifically?

A. Because he's a urologist that works in the urogynecology sphere. We know each other from professional organizations, as well as I'm also a University of Chicago professor, so to speak, and we train -- he also can help train our fellows, and most of my interactions have been through our scientific meetings like AUGS, SUFU, that kind of thing.

MR. JACKSON: I think I have no more questions at this time. I'll reserve the rest of my time.

THE VIDEOGRAPHER: The time is 11:27 a.m., and we are going off video record.

(Brief interruption.)

THE VIDEOGRAPHER: The time is 11:32 a.m., and we are back on the video record.

EXAMINATION

BY MR. SNELL:

Q. Doctor, my name is Burt Snell. We know each other. I just want to follow up on some of the questions that plaintiff's counsel asked you.

Are you prepared to proceed?

A. Yes, I am.

Q. Are you prepared to answer my questions to

the same degree of truthfulness that you answered plaintiff's counsel's questions?

A. Yes.

Q. During your answers to plaintiff's counsel, at certain times you asked if plaintiff's counsel would provide certain documents or if he would allow you to look at certain materials. So some of what I'm going to ask you about pertains to the materials to which you were referencing. I'm just giving you a heads-up where I am going to go. Okay?

A. Yes.

Q. First of all, do you recollect plaintiff's counsel asking you some questions about your opinions as to the adequacy and content of the Ethicon TVT sling IFU?

A. Yes.

Q. And is it your opinion that the Ethicon TVT IFU is adequate to warn pelvic floor surgeons of the potential risks specific to the device?

A. Yes.

Q. Who are the intended users, based upon your expert review and analysis, of the TVT Retropubic stress incontinence device?

A. The intended users are surgeons who have specific training in the treatment of stress urinary incontinence and specific knowledge of the treatments and surgeries for stress urinary incontinence.

Q. Plaintiff's counsel asked you several questions about whether risks were commonly known or not to pelvic floor surgeons; do you recollect that?

A. Yes.

Q. And is that something you investigated and formulated opinions about, the risks that are commonly known for stress incontinence surgeons, including TVT, as to pelvic floor surgeons like yourself?

A. Yes.

Q. You mentioned the various sources of knowledge that a surgeon has with regard to these commonly known risks. Let me ask you this: Are -- is knowledge of those commonly known risks, is that acquired, if at all, in your medical school?

A. Yes, we start learning about surgical risk for varied procedures, including stress incontinence, in medical school.

Q. Is a source of that common knowledge that plaintiff's counsel asked you about with regard to risk of incontinency procedures, does that flow from your learning in residency as a pelvic floor surgeon?

A. Yes. Stress incontinence treatment, surgical and nonsurgical, are part of the core curriculum of residencies.

Q. And same question as to fellowship. Is the fellowship program that a pelvic floor surgeon can undergo, do you know whether or not that is a source of this common knowledge of risk of stress incontinent surgery?

A. Yes, especially in fellowship, that is the source -- that is where we are learning even a higher level of all the risk of incontinent surgeries as well as the procedures. That's where we absolutely can fine-tune our knowledge of all of that.

Q. Have you investigated or read any of the core curriculum and curriculum -- expected curriculum materials for pelvic floor surgeon residencies and fellowships that pertain to the risk of not just TVT but also other incontinent

surgeries?

A. Yes, as part of the core curriculum put out by the ACGME for residency in OB/GYN, as well as fellowships in FPMRS, yes, it's part of the core curriculum that you should know the procedures as well as the complications.

Q. Did you also -- in formulating your opinions, did you also look out and review or consider the American Urologic Association's curriculum regarding stress incontinent surgery that their residents are expected to know of?

A. Yes, I think the American Urologic Association, AUA, core curriculum includes those topics for residents, as well as for the medical students.

Q. And were those sources of your foundations for your opinions as to what risks are commonly known to pelvic floor surgeons with regard to TVT and stress incontinent surgeries?

A. Yes, they are.

Q. Is pain a commonly known potential risk of stress incontinent surgeries?

A. Yes, it is.

Q. Is chronic pain a potential risk that's

commonly known by pelvic floor surgeons of stress incontinent surgeries?

A. Chronic pain is commonly known. It's very rare, but it's known that it could possibly happen.

Q. And have you seen or did you consider the regulation on the labeling for medical devices and whether or not it stated that commonly known risks need not be included in the Instructions for Use?

MR. JACKSON: Objection. Form.

THE WITNESS: Yes, I have seen the -- if you're talking about the FDA regulatory advice on how to write up, it's -- it said it was up to the judgment of the person creating it but does not have to include the commonly known risks.

BY MR. SNELL:

Q. And have -- did you investigate and have you opined on what are the commonly known risks to the intended user pelvic floor surgeon?

A. For the sling?

Q. Yes.

A. Yes, I have.

Q. Now, do you have that Ethicon IFU in front of you, Exhibit 7, that you discussed with plaintiff's counsel?

A. Yes, I do.
Q. On the very first page under "Important," do you see it says that "The IFU is not a comprehensive reference to surgical technique for correcting stress urinary incontinence"?
A. Yes, it does say that.
Q. And is that something you considered in formulating your opinion as to whether the IFU was adequate?
A. Yes.
Q. Is that something you considered in formulating your opinions as to whether the commonly known stress incontinence risk needed to be in the TVT IFU?
A. Yes.
Q. A little further down, it states "Variations in use may occur in specific procedures due to individual technique and patient anatomy"; do you see that?
A. Yes, I do.
Q. Is that consistent or inconsistent with your opinion with regard to the adequacy of the IFU for how to tension or not tension the TVT?
A. Yes.

Q. Plaintiff's counsel asked you a question about whether the TVT IFU contraindicated its use in women who are obese; do you recollect that?

A. Yes.

Q. Is there any Level 1 or Level 2 or reliable evidence that you are aware of that shows the TVT is not effective in obese women?

A. No, there is not.

Q. To the contrary, have you investigated the medical literature to determine whether TVT is efficacious and safe in women who are normal weight, overweight or who may be obese?

MR. SNELL: Objection. Form.

THE WITNESS: Yes, there is literature that supports the use in varied weight.

BY MR. JACKSON:

Q. Do you recall plaintiff's counsel asked you some questions about tensions, and I believe you testified that you did not want tension of the TVT once it was placed?

A. Correct.

Q. If you look at the bottom of this paragraph, on page number 27, I'm just going to read it into the record where it's talking about

Instructions for Use, actually placing the device.

The last paragraph on page 27 says "To avoid putting tension on the tape, a blunt instrument (scissors or forceps) should be placed between the urethra and the tape during removal of the plastic sheath"; do you see that?

A. Yes.

Q. "Premature removal of the sheath may make subsequent adjustments difficult"; do you see that?

A. Yes.

Q. Is that part of the IFU that you considered in formulating your opinions?

A. Yes.

Q. Is that part of the IFU actually consistent or inconsistent with your opinions that you do not want to put the TVT in with tension ultimately?

A. I think it's consistent with my opinion.

Q. Is it consistent with your technique that you described to plaintiff's counsel?

A. Yes, it is consistent with my technique.

Q. Is that something you've learned during the Ethicon professional education with regard to TVT and how to space or provide space between the

tape and the urethra?

A. They did give instruction and basically made the point of do not tension it, to leave space.

Q. On the first page, this also says that "The device should be used only by physicians trained in the surgical treatment of stress urinary incontinence"?

A. Yes.

Q. "And specifically in implanting the Gynecare TVT"; do you see that?

A. Yes.

Q. Is that something you read and considered in formulating your opinions as to the adequacy of the IFU to pelvic floor surgeons?

A. Yes.

Q. Is that something you also considered in formulating your opinions as to the adequacy of the IFU as to pelvic floor surgeons specifically with regard to the risk that would already be commonly known?

A. Yes.

Q. And because the IFU specifically says that surgeons should be trained or receive some

education on the TVT device, do you consider that professional education, training, the surgical videos, the slides and other curricula, to supplement the actual text of the IFU?

A. Absolutely.

Q. In the warning section, Warning No. 3 says "Users should be familiar with surgical technique for bladder neck suspensions and should be adequately trained in implanting the TVT device"; do you see that?

A. I'm sorry. Is it on the same page?

Q. I'm sorry. Page 28, the third bullet point under "Warnings."

A. Thank you.

Yes, I do see that.

Q. And it says "It's important to realize that TVT is different from the traditional sling procedure in that the tape should be located without tension under the midurethra"; do you see that?

A. Yes.

Q. Is that an accurate statement, first of all, that "TVT is different than the traditional sling procedure in that it's located without

tension under the midurethra"?

A. That is true.

Q. And did you consider that in formulating your opinions as to the adequacy of the TVT IFU?

A. Yes.

Q. Did you consider that in formulating your opinions as to whether that needed to be warned of, that there was a clear difference, according to your analysis and investigation, between the TVT and the traditional sling in that regard?

A. That's one of the most important points between -- the difference between the retropubic TVT and a pubovaginal sling. So that is something I feel is important to be on the IFU.

Q. The third-to-last bullet point discusses that "To minimize risk, make sure to place the tape tension free in the midurethral position"; do you see that?

A. Yes.

Q. Is that something you considered in formulating your opinions as to the adequacy of the TVT IFU?

A. Yes.

Q. Is that consistent or inconsistent with

the opinions you expressed earlier with regard to not wanting to tension the TVT device?

A. That's consistent with.

Q. You were asked some questions about -- let's go to the mechanical versus the laser -- laser cut issue first.

Do you recollect covering that subject with plaintiff's counsel?

A. Yes, I do.

Q. Turn to your report at page 32.

A. Okay.

Q. Page 3, you have a section titled "Mechanical Versus Laser Cut"?

A. Yes.

Q. You state that the TVT sling was mechanically cut beginning between 1998 and 2007, and that after the introduction of laser cut, Ethicon continued to make and sell mechanically cut mesh as well, and that Ethicon still sells both mechanical cut and laser cut TVT in order to satisfy surgeon preferences; do you see that?

A. Yes, I do.

Q. Now, earlier -- let me ask you this: Does that refresh your recollection as to whether it's

your opinion or understanding, based on your review of the Ethicon documents and other sources, as to whether the mechanical cut mesh is still available for the TVT Retropubic device?

MR. JACKSON: Objection. Form.

THE WITNESS: Yes, it does.

BY MR. SNELL:

Q. Fair to say you've reviewed a lot of Ethicon documents?

MR. JACKSON: Object to form.

THE WITNESS: Yes, I have.

BY MR. SNELL:

Q. Binders and binders full?

A. And thumb drives and thumb drives full.

Q. Plaintiff's counsel asked you about any studies that were specific or addressed the mechanical cut versus laser cut issue for the mesh; do you recall that?

A. Yes.

Q. Did you identify at page 32 and 33 of your report studies that you were able to find in the literature that looked at mechanical cut versus laser cut mesh and whether there was a clinically significant difference between the two?

A. The Neuman -- the Agarwal studies.
Q. And --
A. Then there is an Thubert study that we identified that looks specifically at mechanical versus laser cut.
Q. The Thubert study, can you just tell us does that concern TVT or TVT EXACT?
A. TVT versus TVT EXACT.
Q. Is that the study you were referencing earlier to plaintiff's counsel?
A. I think so.
Q. Did that study show a significant difference in the exposure rate between the TVT and newer TVT EXACT laser cut?
A. At 12 month follow-up, both of them had a zero percent exposure rate.
Q. Is that a study you considered in formulating your opinion that there has been no demonstrated clinically significant difference between mechanical and laser cut mesh for the TVT Retropubic device based upon the reliable literature?
A. Yes.
Q. In your review of these issues, do you

recall seeing the -- do you know what TVT Abbrevo device is?

A. Yes, I do.

Q. Do you recall looking at the de Leval-Waltregny TVT-O versus the TVT Abbrevo device clinical study that assessed things like rates of exposure at one year and three years?

A. Yes, I do recall that.

Q. Is the Abbrevo, do you have an understanding whether that's only laser cut too?

A. That is -- that is only laser cut.

Q. And do you have a recollection as to whether those -- that study that actually compared the older TVT-O with the TVT Abbrevo, whether it showed any difference, statistically significant difference in complication rates pertaining to rates of exposure or erosion?

A. There was no difference in rates of exposure.

Q. Do you also -- is that -- does that form part of the basis of your opinion that there has been no reliably demonstrated clinically significant effect for the mechanical versus laser cut mesh for TVT?

A. Yes, yes.
Q. You were asked a question about the AUGS/SUFU Position Statement and the reference in your report that TVT is a large bore, lightweight mesh; do you recall that?
A. Yes.
Q. Do you -- can you turn to -- I think it's No. 55 in your binder.
A. I think I also have it right here. I have it right here, yeah.
Q. The sentence in the AUGS/SUFU Position Statement where it references the midurethral sling as a large pore, macroporous lightweight mesh, can you find that in that document for me?
I believe it's on the second page --
A. Yeah.
Q. -- under Item No. 1.
A. One, yes.
Q. And do you see there is a reference after that?
For the record it says "As a knitted implant for the surgical treatment of SUI, macroporous, monofilament, lightweight polypropylene has demonstrated long-term

durability, safety and efficacy up to 17 years," with a reference eight. Do you see that?

A. Yes. That's Dr. Nillson's 17-year study of TVT Retropubic.

Q. Is that the TVT Retropubic device -- specific device you rendered opinions on here today?

A. Yes, it is.

Q. And did this physician statement include any other data on the TVT device?

A. Yes, it does.

Q. Any Level 1 data?

A. Yes, there is. It includes the -- actually, multiple, the Ward study, the Ward-Hilton study, the Novara review, which includes some of the TVT --

Q. There is a reference to the Ogah-Cochrane review. I believe you discussed that with plaintiff's counsel already?

A. Right, that was -- Ogah-Cochrane review yes.

Q. Was that the same --

A. 2009 Cochrane Review that we were discussing, yes.

Q. And did you investigate whether the larger pore, supposedly lighter weight meshes for hernia or prolapse, whether they had been demonstrated to be as effective as TVT in the application of a stress incontinence sling?

MR. JACKSON: Object to form.

THE WITNESS: Yes.

BY MR. SNELL:

Q. And did you find any data that supported the conclusion -- strike that.

What is your opinion with regard to whether the ULTRAPRO and Vypro have been demonstrated to be as safe and effective as TVT?

A. In the ULTRAPRO and Vypro study, they actually had a higher erosion rate, a 4 percent versus the 2 percent of the TVT Retropubic. So in my opinion it does not prove it is as safe.

Q. And have any of the other meshes, larger pore or lighter weight absorbable meshes been shown to be as effective and durable and been studied as long as TVT?

A. No, nothing has.

Q. Is it desirable to surgeons, like yourself, that the TVT has been studied in multiple

long-term studies?

A. It very much is, yes.

MR. SNELL: Let's go off the tape.

THE VIDEOGRAPHER: The time is 11:55 a.m. This is the end of Tape 2, and we are going off the video record.

(Brief interruption.)

THE VIDEOGRAPHER: The time is 12:00 noon, and we are back on the video record.

BY MR. SNELL:

Q. Doctor, do you recall being asked questions about the Cochrane Reviews and, for example, whether data for a device called SPARC was included?

A. Yes.

Q. And whether TVT was included as well?

A. Yes, I do.

Q. Do you have in front of you the Ogah-Cochrane review?

A. Yes, I do.

Q. Is that -- first of all, based on the level of evidence you've described to plaintiff's counsel, what level of evidence is that?

A. It's Level 1.

Q. Is there anything higher than Level 1 evidence?
A. No.
Q. Did you try to formulate your opinions on the highest level evidence that you could find?
A. Yes.
Q. Did this Cochrane -- was it a systematic review of meta-analysis?
A. Yes, it is.
Q. Did it investigate the efficacy and safety of the TVT Retropubic device upon which you've rendered your opinions?
A. Yes.
Q. Did it compare the actual TVT Retropubic device to the SPARC device?
A. Yes, there is a study in there.
Q. What, if anything, did it show -- did the TVT show as compared to the SPARC?
A. The retropubic TVT had a higher success rate and less voiding dysfunction, less spotter perforations and less tape erosions than the SPARC procedure.
Q. Is that something you considered in formulating your opinions in this case?

A. Yes.
Q. Did that Cochrane review also investigate the safety of monofilament tapes, like TVT, compared to multifilament tapes, like others that use polypropylene, Monocryl, Vicryl or various multifilament tapes?
MR. JACKSON: Objection. Form.
MR. SNELL: Strike that.
BY MR. SNELL:
Q. Did that Cochrane review compare the monofilament tapes, like TVT, to multifilament tapes?
A. Yes, it did.
Q. And what, if anything, did it show you?
A. It showed the monofilament tapes -- tapes showed fewer tape erosions than the multifilament tapes.
Q. What was the rate of erosion with the monofilament tapes?
A. The relative risk for the monofilament tape was 1.3 percent, so 30 percent higher.
Q. So the rate of erosion with the monofilament was 1.3 percent?
A. No, so the relative risk -- I have to look

up the exact rate. Sorry. I have to find Figure 6. Sorry.

So this, you know, gives the relative risk of 1.3 percent, which is usually a 30 percent higher risk. It doesn't give the exact rate of erosion.

Q. Can I see --

A. I don't think.

Q. Can I see that Cochrane review?

A. Uh-huh. Unless I'm just missing it.

Q. It states "Monofilament tapes had fewer tape erosions (1.3 percent versus 6 percent) with the RR of 0.25"; do you see that?

A. Okay. Sorry. I was looking right past it.

Q. So the rate for the monofilament -- so the rate for the monofilament tapes was 1.3 percent?

A. Correct.

And the multifilament was 6 percent.

Q. And the RR of 0.25, what does that mean?

A. It's a quarter of the percentage, one fourth.

Q. Do you have the Ford-Cochrane review for 2015 that you referenced with plaintiff's counsel

handy?

A. Yes, I do.

Q. I just want to turn your attention to page 10.

You were asked questions about whether the TVT is a macroporous mesh. Do you recollect that?

A. Yes.

Q. You were shown a document that it included in a microporous category; do you recall that?

A. Yes.

Q. Is that a document you had seen before even here today?

A. Yes.

Q. Is that a document that you disagree with?

A. Yes.

Q. And did you consider and look to see whether the Cochrane review identifies whether TVT would be a macroporous or a microporous mesh?

A. Yes. According to the Cochrane review, the Ford review, it's a macroporous Type I mesh.

Q. Is that consistent or inconsistent with your opinion?

A. That's consistent with my opinion.

Q. Does the Cochrane review state whether

macroporous mesh, like the TVT, is biocompatible?
A. Yes, it does. It says it has biocompatibility and low risk of infection.
Q. Do you agree with that statement?
A. I do.
Q. Is that a statement -- is that an opinion you formulated based upon your own independent analysis of the literature and data?
A. Yes, based on the Level 1 data.
Q. Is that an opinion you hold and rely upon for your earlier expressed opinions that the reliable data do not show degradation or a clinically significant long-term chronic inflammatory effect of the TVT device?
A. Yes --
MR. JACKSON: Objection. Form.
THE WITNESS: Yes, it is.
BY MR. SNELL:
Q. Can you tell us what level of evidence is the Ford-Cochrane review?
A. Level 1.
Q. Do you recall being asked questions about the pore size of TVT?
A. Yes.

Q. I think you earlier stated that the pore size of TVT was between 1100 and 1300 microns, but the Moalli study would have measured it more specifically?

A. Yes.

Q. If the Moalli study identified the pore size of the TVT Retropubic device at greater than 1300 microns, would that be consistent or inconsistent with your general understanding and recollection of what you had viewed its pore size to be?

A. That's more accurate than my view, of course.

Q. You were asked questions about specific studies that would have looked at longer term or chronic pain; do you recall that topic?

A. Yes.

Q. Is that something you investigated in formulating your opinions?

A. Yes.

Q. Look at your report at pages 27 and 28.

At page 28 you identify a meta-analysis by Tommaselli?

A. Yes.

Q. And you say "It was a systematic review of long-term studies"; do you see that?
A. Yes.
Q. Was the TVT device included in that study or in that meta-analysis?
A. Yes, it was.
Q. Do you have a recollection of the 3,974 retropubic cases, how many were -- how many of those was persistent or chronic pain present in?
A. 13, which is .3 percent.
Q. And do you believe that 0.3 percent to be a reliable number?
A. Yes.
Q. What level of evidence is the Tommaselli systematic review in that analysis?
A. That's Level 1 evidence.
Q. Do you have a general recollection as to whether there was one or two TVT Retropubic long-term studies or multiple ones?
A. There is multiple TVT long-term studies.
Q. More than 10 or 20?
MR. JACKSON: Objection. Form.
THE WITNESS: Yes, definitely more than 10.

BY MR. SNELL:

Q. You recall being asked questions about certain studies and whether they had a primary end point of safety or dyspareunia or pain?

A. Yes.

Q. And you identified that primary end points are something that are specific to a randomized control trial?

A. Yes.

Q. Let me ask you this: Did you look at meta-analyses or database studies whose primary -- one of the primary purporting goals was to report rates of dyspareunia or pain?

A. So in saying "primary end point of the studies," I'm thinking of the components of the meta-analysis. So the randomized control studies were looking at the studies -- especially, like, just one randomized controlled study, usually, you can't power it with enough patients. So therefore you have to have a meta-analysis where they look at all these different components. So a meta-analysis primary end point is different than a randomized controlled trial primary end point. They have enough volume to actually look at different

components.

Q. And is that, in your opinion, the best, most highest level of evidence of what the rate of that complication would be?

A. Yes --

MR. JACKSON: Objection. Form.

THE WITNESS: Yes. Absolutely.

BY MR. SNELL:

Q. You reference, for example, at the bottom of page 28, the Unger 2015 study. Is that a study of a database -- database-type study?

A. Yes, it is.

Q. Where the rate of women requiring revision for pain -- vaginal pain or dyspareunia was 0.2 percent; do you see that?

A. Yes.

Q. And, actually, is that number consistent or inconsistent with the Tommaselli number of 0.3 percent long term?

A. Consistent.

Q. And did you find that number, 0.2 percent, to be reliable as to the longer term rate of pain or dyspareunia that requires a reoperation?

A. Can you repeat that?

Q. Yeah.

Did you find the 0.2 percent rate reported by the Unger paper to be a reliable indicator of the longer term chronic pain in that database study?

A. Yes, I do.

Q. Page 29, you have the Laurikainen 2014 randomized control trial; do you see that?

A. Yes.

Q. Do you have a recollection as to whether that was the five-year TVT specific study?

A. Yes, I believe it was five years.

Q. Did you consider the dyspareunia rate in that long-term study in formulating your opinions?

A. Yes.

Q. Svenningsen, you identify a ten-year study, did it have any rate of long-term dyspareunia?

A. No, it did not.

Q. Serati, another ten-year prospective TVT study, is that something you considered as well?

A. Yes.

Q. The Nguyen, spelled N-g-u-y-e-n, did they report that any patients in that database had to

have an excision due to pain?

A. 1 out of 2,339 for a .02 percent excision for pain.

Q. Is that consistent or inconsistent with your opinion that the rate of dyspareunia and chronic pain is below 1 percent for TVT?

A. That's consistent.

Q. And do you cite other data in your report, like the Schimpf meta-analysis and the AUA 2012 meta-analysis?

A. Yes.

Q. And the Schimpf meta-analysis, the AUA 2012 meta-analysis, what -- what level of evidence are those, if any?

A. They are a Level 1.

MR. SNELL: Let's go off the record. Just give me a quick second.

THE VIDEOGRAPHER: The time is 12:15 p.m., and we are going off the video record.

(Brief interruption.)

THE VIDEOGRAPHER: The time is 12:20 p.m., and we are back on the video record.

BY MR. SNELL:

Q. Doctor, I just have one or two more

questions.

Do you recall being asked about your personal use of the TVT Retropubic device?

A. Yes, I do.

Q. And the need to do a revision or excision of TVT or other retropubic midurethral slings?

A. Yes, I do.

Q. Do you have a general estimate as to the number of TVT Retropubic-specific devices that you have excised or removed in your career?

And I only want your estimate as to TVT Retropubic.

MR. JACKSON: Objection. Form.

THE WITNESS: So for TVT Retropubic, I believe I have only revised or excised about five.

BY MR. SNELL:

Q. And I believe you earlier identified for the TVT Retropubic device, your best estimate is you've performed 1,000 to 1,500 of that device over your entire career?

A. Yes.

Q. The five TVTs that you recollect, as your best estimate, that you had to revise or excise, how do you give us that estimate of five?

A. I always kept track based on counseling for my future sling patients, and they were just so few and far between, it was easy to keep track of them and tell a patient I have to excise or revise one once every three or four years.

Q. Last topic.

Plaintiff's counsel asked you some questions about the rate of mesh exposure with the TVT device and your disagreement with him that the rate varies greatly; do you recall that subject?

A. Yes.

Q. Just so the record is clear, at page 27 of your report, you have a paragraph about what you believe the rate of exposure to be with TVT; is that correct or not?

A. Yes, I do.

Q. And are those the particular data sources you rely upon for your opinion with regard to the rate of TVT being 1 to 2 percent, with 2 percent being the most common?

A. Yes, it is.

Q. And are those -- how would you categorize those literature or sources that you have utilized in formulating your opinion with regard to the rate

of TVT mesh exposure?

A. These are primary Level 1 evidence, maybe a little bit of Level 2 evidence, primarily Level 1.

Q. And do those studies, do they cover both short- and long-term studies?

A. Yes, these cover short and over ten-year studies.

MR. SNELL: That's all the questions I have. Thank you.

FURTHER EXAMINATION

BY MR. JACKSON:

Q. Doctor, when Ethicon's counsel was just asking you questions about literature, do you recall him asking a question about the Nillson study of 17-year data?

A. Yes.

Q. And, Doctor, to your knowledge, did that study involve the mechanically cut TVT Retropubic device or the laser cut TVT Retropubic device?

A. To my knowledge, it's the mechanical cut.

Q. And would that study be exclusively mechanical cut?

A. I believe based on the time period -- I'm

not 100 percent certain -- but based on the time period, I believe it's mechanical cut.

Q. Doctor, have you reviewed any studies that compare laser cut mesh and mechanically cut mesh in the TVT-R device?

MR. SNELL: Object. Asked and answered.

THE WITNESS: Specifically, just the TVT-R?

BY MR. JACKSON:

Q. Correct.

A. Not the TVT EXACT, you mean?

Q. Correct.

A. I have in the past. I believe I have in the past, and right off the top of my head, I can't think of them right now. I'm sorry.

Q. Doctor, when Ethicon's counsel was asking you questions about literature, do you remember being asked about a study involving the TVT-O and the TVT Abbrevo, which looked at rates of exposure?

A. Yes.

Q. And is it fair to say that study did not involve the TVT Retropubic device?

A. Yes.

Q. Doctor, when Ethicon's counsel was asking you questions about the five revision surgeries you

have performed, do you remember that line of questioning?

A. Yes.

Q. Okay. Did you report those five revision surgeries to Ethicon?

A. No, I did not.

Q. Okay. Did you report those five revision surgeries to the FDA?

A. No, I did not.

Q. Okay. Are you aware, Doctor, of underreporting of adverse events in regards to the TVT Retropubic device?

MR. SNELL: Objection. Foundation.

THE WITNESS: The concept of underreporting?

BY MR. JACKSON:

Q. Yes.

A. Yes.

Q. And, Doctor, is it fair to say that if you, yourself, did not report those revision procedures to Ethicon or the FDA, that there may be other surgeons who did not report those revision procedures to Ethicon or the FDA?

MR. SNELL: Object. Requires speculation.

THE WITNESS: Yes, I would assume there are.

BY MR. JACKSON:

Q. And, Doctor, all the literature you've cited can only include known complications, correct?

MR. SNELL: Objection on that one too.

BY MR. JACKSON:

Q. Doctor, I'm sorry. Let me ask a better question. Strike that.

Doctor, if the author of a study wants to provide an erosion rate, how do they come up with that erosion rate?

A. So depending on the study, most of the studies are -- erosion rate is detected on examination, so physically seeing the patient and identified on the examination.

Q. And, Doctor, the -- sorry. Strike that.

Doctor, would the five revision procedures you performed yourself on TVT Retropubic devices be included in any of the literature you cited?

A. Those patients were not part of studies, and they were also not erosions.

MR. JACKSON: We had previously marked as Exhibit 5 a binder that the doctor had brought with her. There is a second binder that she brought on

the table. If we could mark that as Exhibit 13.

(Whereupon, TOMEZSKO Exhibit 13 was marked for identification.)

BY MR. JACKSON:

Q. And, Doctor, I believe you also brought some thumb drives with you today?

A. Yes.

Q. Could we mark those as Exhibit 14, please.

(Whereupon, TOMEZSKO Exhibit 14 was marked for identification.)

BY MR. JACKSON:

Q. Could you just let us know how many thumb drives are in that bag?

A. There is four.

MR. SNELL: Should we mark them collectively A, B, C, D?

MR. JACKSON: Yeah, let's do that.

BY MR. JACKSON:

Q. And, Doctor, is it your understanding that the two binders you have in front of you -- I'm sorry. Strike that.

Doctor, the two binders you have in front of you, can you just identify the materials that are in what we just marked as Exhibit 13, the

second binder? Could you just generally let me know that what is?

A. It's -- some of it is duplicative of the other binder. It's primarily the -- just more the research trials, literature.

Q. Okay. And, Doctor, I believe you also brought a box of documents, which is on the floor; is that correct?

A. Yes.

Q. And are those copies of Ethicon depositions and documents?

A. Yes.

Q. Okay. And are those same documents also included on the flash drives, to the best of your knowledge?

A. To the best of my knowledge, yes.

Q. And, Doctor, do you believe that the reliance list you provided in this case is comprehensive of all of the materials you reviewed in this case?

A. To the best of my knowledge.

Q. Okay. Thank you.

MR. JACKSON: I have no more questions.

MR. SNELL: I just have a question or two.

FURTHER EXAMINATION

BY MR. SNELL:

Q. Plaintiff's counsel asked you a question about your five cases with TVT of the revisions or whatever type of surgery they were. Did you look in the literature for studies and databases that would pick up whether there was a sling release or not, regardless of whether the surgeon reported it as an adverse event or whether the patient even returned back to the same surgeon?

MR. JACKSON: Objection. Form.

THE WITNESS: Yes. So most of the large studies are comprehensive in capturing patients or there are other database studies that basically are capturing patients through insurance data. So they are inclusive of whether the patient went back to the same surgeon or not. So I feel they are very comprehensive in actually capturing what patients have revisions or required erosion surgery.

BY MR. SNELL:

Q. And did you look at those different database studies to see whether their rates were consistent or inconsistent with the other data?

A. Yes, I do, and they are all consistent

with 2 percent.

Q. Page 27, you identify -- I'm just going to give an example -- the Jonsson-Funk 2013 database study, nine-year study; do you see that?

A. Yes.

Q. Did you consider that to be a long-term study?

A. Yes.

Q. Did you -- was that a study in a large enough group of patients that it was significant in your opinion?

A. Yes, absolutely.

Q. Do you have a recollection of roughly how many patients were in that study? Was it less than a 100? More than 1,000?

A. I believe that was the 185,000 patients.

Q. Pretty big study?

A. Very big study.

Q. And so do you feel that the rates you've reported and established in your opinions with regard to the complications, as well as reoperation rates, are reliable?

A. Yes, I do.

MR. SNELL: I have no further questions.

MR. JACKSON: I have no further questions.

THE VIDEOGRAPHER: Okay. The time is 12:32 p.m. This is the end of Tape 3. It's also the end of the deposition of Dr. Janet Tomezsko, and we are going off the video record.

C E R T I F I C A T E

I, DEANNA AMORE, a Shorthand Reporter and notary public, within and for the State of Illinois, County of DuPage, do hereby certify:

That JANET TOMEZSKO, M.D., the witness whose examination is hereinbefore set forth, was first duly sworn by me and that this transcript of said testimony is a true record of the testimony given by said witness.

I further certify that I am not related to any of the parties to this action by blood or marriage, and that I am in no way interested in the outcome of this matter.

IN WITNESS WHEREOF, I have hereunto set my hand this 28th day of June, 2016.

_____

Deanna M. Amore, CSR, RPR

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

JANET TOMEZSKO, M.D. DATE

Subscribed and sworn
to before me this
_____ day of _____, 20____.
My commission expires:_____

_____

Notary Public